UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MATTHEW C. ZORN, Plaintiff, v. U.S. DEPARTMENT OF JUSTICE, ET AL. Defendants.	§ § § § § § § § § §	Civil Action No. 4:22-cv-02396

DECLARATION OF MATTHEW C. ZORN

1. My name is Matthew C. Zorn. I am over 18 years of age, of sound mind and fully competent to make this Declaration. I have never been convicted of a felony or a crime of moral turpitude. I have personal knowledge of all the facts stated herein, and they are true and correct to the best of my knowledge. I am the Plaintiff.

2. I incorporate my prior declaration by reference, Dkt. 28-1, which to my knowledge, is still true and correct.

General Background

3. I am a partner at Yetter Coleman LLP in Houston, TX. I graduated from Columbia Law School in 2012. Following graduation, I worked for 3.5 years as a litigator at Paul, Weiss, Rifkind, Wharton & Garrison. From 2016 to 2017, I served as a judicial law clerk for Chief Judge Rodney Gilstrap of the Eastern District of Texas. Following the clerkship, I began my practice at Yetter Coleman LLP in 2017 and was elected partner in 2022. The American Lawyer named me a finalist for Young Lawyer of the Year (Litigation) in 2021, and the American Inns of Court named me a 2020 Pegasus Scholar.

4. I am recognized as an authority on issues relating to the federal Controlled Substance Act. I speak about it frequently. Over approximately the past year, I've done at least 5 podcasts and been a speaker at 5 industry conferences. Also, with Shane Pennington, I recently published an article on the unconstitutionality of 21 U.S.C. § 811(d) entitled The Controlled Substances Act: An International Private Delegation That Goes Too Far, 100 Wash. U. L. Rev. (2023).

5. In addition to my private practice, I publish on an online newsletter entitled "On Drugs" at ondrugs.substack.com, which I co-founded with Shane Pennington. Thousands read On Drugs. Most material is free. Topics range from IP to taxes to issues about the Controlled Substances Act. In writing for On Drugs, I apply my niche expertise in controlled substances to distill legal filings, including administrative filings, for those interested in legal developments in drug policy. Although I have no way to prove this, On Drugs may be the most widely read

publication that has a specific focus on legal issues in the controlled-substances space. DEA has granted me media status for at least some of my FOIA requests. And I have been given press credentials at an industry conference.

6. Although DEA proceedings nominally default to public—i.e., nothing prevents the media or members of the public from attending hearings—unlike a court case or proceedings before other agencies engaged in enforcement, the existence of DEA proceedings is not disclosed on any website or publicly accessible medium that I am aware of. Nor are the dockets or case filings. If I knew about filings in these proceedings and the records could be obtained in timely fashion without having to pay thousands or tens of thousands of dollars to get them, I might write essays breaking down legal concepts discussed therein as I have with many other legal topics in the drug-policy space. I could also inform others about the agency law.

7. Over the past year, I have made more than a dozen FOIA requests to DEA. The DEA FOIA portal lists 16 requests going back to 2022. Some remain open and pending. Some have been "Assigned for Processing," and some are "In Process." My December 2022 request for "the 2022 electronic calendar/scheduler of Administrator Milgram and Deputy Administrator Milione (e.g., a Calendar export from Outlook) from January 1, 2022 to December 31, 2022," for example (Request No. 23-00213-F), is "In process."[1]

8. Below, I discuss some of these requests relevant to my pending claims and background/circumstances relating to them and my filing of this action.

DEA's Star Chamber

9. I have personal knowledge of DEA proceedings and how they are conducted having recently participated in one, as outlined below. Here is a quick rundown. Filings are done through e-mail, ECF-DEA@DEA.gov. There is no central docket like PACER. There is no publicizing of the hearings, except as provided in the Federal Register. Prehearing conferences are often conducted off-the-record. There is no discovery. Exculpatory evidence need not be disclosed. *See generally Miami-Luken, Inc. v. DOJ/DEA*, 2018 WL 5283938, at *2 (S.D. Ohio Oct. 24, 2018) (explaining process).[2] The Government didn't turn over its exhibits until around 10 weeks before the hearing according to a disclosure deadline, even though I had FOIA requests directly calling for many of them and they were easy to transmit.

10. One peculiar procedural point about these proceedings deserves highlighting and explanation. Under 21 CFR § 1316.62, any party in a DEA proceeding may seek interlocutory review by the Administrator of ***any*** ALJ decision. A party must first request consent from the ALJ. But even if the presiding ALJ denies an interlocutory appeal, the determination is routed to the Administrator for discretionary review. The DEA Administrator may then determine an appeal is warranted under the section, accept the interlocutory appeal, and overrule the ALJ's ruling.

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[1] On December 27, 2022, the agency deemed my rote request for an Outlook export of the calendar to raise "unusual circumstances."

[2] *See also Miami-Luken, Inc. v. DOJ*, 2016 WL 3855205, at *9 (S.D. Ohio July 15, 2016).

11. In this way, all ALJ rulings in a DEA enforcement hearing are subject to review by DEA's Administrator. All the Government must do is ask.

12. Whether this odd arrangement comports with Due Process is an interesting question. It likely violates the 5 U.S.C. § 554(d) of the APA, which provides that an employee presiding over the reception of evidence under § 556 cannot be "subject to the supervision or direction of an employee or agent engaged in the performance of investigative or prosecution functions for an agency" and an employee or agent engaged in the performance of investigative or prosecuting functions for an agency may not participate or advise in a decision, recommendation, or agency review under § 557. DEA's Administrator and the Administrator's office are likely involved in the performance of investigative and prosecuting functions in nearly every case. So, by subjecting all ALJ rulings to supervision by the DEA Administrator before the issuance of a recommended decision, DEA's unique process appears to violate § 554(d).

13. Equally important, 21 C.F.R. § 1316.62 is a recent addition to DEA's regulations, and its origins are quite instructive and illustrative. In the *Miami-Luken* matter, the ALJ denied a request for an interlocutory appeal by DEA's counsel seeking to quash a subpoena issued by the ALJ. DEA's Acting Administrator stepped in and issued an order that purported to quash the subpoena—after a federal district court had ordered DEA to comply. *See Miami-Luken, Inc. v. DEA*, 900 F.3d 738, 739-41 (6th Cir. 2018). DEA was unsuccessful in overturning the ALJ's subpoena in federal district court. Despite being ordered by a federal judge to produce the documents, DEA disregarded the order, prompting the court to remark that "DEA's brazen disregard of this Court's previous Orders and actions in this case border on sanctionable." *Miami-Luken, Inc. v. DOJ*, 2019 WL 78990, at *1 (S.D. Ohio Jan. 2, 2019). *See also Miami-Luken, Inc*, 2018 WL 5283938, at *12 ("[T]he DEA moves beyond vigorously advocating its position and comes dangerously close to violating Fed. R. Civ. Proc. Rule 11").

14. Hence, the promulgation of 21 C.F.R. § 1316.62 months later (84 Fed. Reg. 18138), which now allows the Administrator to overrule *any* ALJ decision (such as a subpoena requiring the production of potentially exculpatory evidence) upon request by the agency, thus sidestepping the annoyance of federal-court supervision and meaningful judicial review.[3]

The Five Tryptamines Rulemaking

15. From January to August 2022, I represented two biotech/pharmaceutical startups developing technology related to psychedelic medicine in a public, formal rulemaking proceeding. 87 Fed. Reg. 2376. In brief, DEA initiated a rulemaking to place five substances onto Schedule I. Not only was the evidence supporting the decision remarkably thin, but the Administrator's actions were plainly *ultra vires*. The Administrator proposed placing these substances on Schedule I in 2022 based on an outdated ***2012*** medical/scientific evaluation from HHS, even though the plain text of the Controlled Substances Act requires DEA to obtain an evaluation with *current*

[3] I further note that the agency promulgated the new interlocutory appeal rule that effectively gives the Administrator plenary review and made it effective immediately. As a rule of agency procedure or practice that purportedly did not "create any substantive right in a party beyond those already existing under 21 C.F.R. 1316.62," did not submit the rule to the normal notice-and-comment process. 84 Fed. Reg. at 18139.

medical/scientific evidence before initiating scheduling proceedings. *See* 21 U.S.C. § 811(b), (c) (requiring DEA to seek HHS evaluation/recommendation on factors that include "*current* scientific knowledge" and "*current* pattern of abuse").

16. On April 4, 2022, I raised a procedural issue with DEA's attorney about the agency's compliance with 21 C.F.R. § 1308.43(f), which requires the notice of any proposed rulemaking "include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to § 1308.44." DEA's notice had not included this important information, which would inform the public of the time/place of the hearing and their right to participate in it. *See* 21 C.F.R. § 1308.44. Along the lines of the Supreme Court's *Niz-Chavez* decision, I informed the Government that the notice was defective because it had to include all the required information, so it needed to publish a new one.

17. The tribunal held an off-the-record status conference on April 26, 2022 in which the issue was discussed. The Government lawyer explained that DEA was in the process of publishing a compliant notice of hearing in the Federal Register.

18. Not so. By June 13, DEA had published nothing. So, the ALJ ordered DEA to publish a notice with the following text:

> The Drug Enforcement Administration is convening a hearing on the Notice of Proposed Rulemaking, 87 Fed. Reg. 2376 (2022), proposing to place 4-hydroxy-*N,N*-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-*alpha*-methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-*N,N*-diethyltryptamine (5-MeO-DET), and *N,N*-diisopropyltryptamine (DiPT) in schedule I of the Controlled Substances Act. Notice is hereby given that a hearing in connection with the proposed scheduling action will commence on August 22, 2022 at 9 a.m. Eastern Time at the Drug Enforcement Administration Hearing Facility in Arlington, Virginia. The hearing date is subject to change to a later date and no additional announcement will be published. *See* 21 C.F.R. § 1316.53.

19. DEA did not do this, so the ALJ called for an on-the-record status conference. At the June 27 conference, as the Ex. 1 shows, DEA's counsel disclosed that someone from the Administrator's office (and perhaps the Administrator herself) instructed DEA's counsel to disregard the ALJ's order. Hearing a Government attorney state that the head of a federal agency expressly instructed him to disregard an ALJ's order—an order that merely required DEA to publish a document disclosing the time/date of a proceeding to allow others to participate—is possibly the single most bizarre and mystifying thing I've witnessed in my decade's worth of practicing law. Three days after DEA's counsel disclosed the instruction, he withdrew from the case, subsequently left DEA, and started working at another position within DOJ.

20. Following distribution of the on-the-record status conference, on July 27, 2022, DEA terminated the proceeding. 87 Fed. Reg. 45076. Thus, it is no longer pending. DEA terminated the hearing days after (a) an investigative reporter from Newsweek reached out to DEA after reading the July transcript and (b) I filed this lawsuit.

21. During the proceedings, I made several FOIA requests to support my clients. Many simply requested important documents in DEA's administrative file, which I knew it had, were readily accessible, and could be produced with a click. DEA used the "unusual circumstances" policy, however, to defer my request and otherwise refused to disclose those documents to me until the disclosure deadline.

22. Another of my requests, No. 22-00560-F sought "all ***filings*** from the proceedings in Administrative Law Judge (ALJ) Docket No. 10-46 described in 76 Fed. Reg. 77329 (Docket No. DEA-333), including briefs filed and all ALJ orders, such as the ALJ decision (Date Range for Record Search: January 13, 2015 to January 13, 2011)." I made this request because the records related to a prior formal rulemaking involving a different substance (i.e., it was precedent I could use and learn from).

23. As was the case with all my requests during this time, DEA stated that my request raised unusual circumstances and that it would not respond within the default statutory time limits. It provided a response on September 16, 2022, a true and correct copy of which is attached as Ex. 2 to this declaration. In the response, DEA asserts that my request for public filings was for a "commercial use" and demanded I pay a check or money order up front in the amount of $41,960 to access these public administrative proceeding records.

24. My inability to obtain these records and information from other DEA proceedings directly interfered with my advocacy and the interests of clients in concrete, tangible ways. For example, after DEA challenged one of my client's standing in the rulemaking proceeding, I needed to submit confidential business information to substantiate standing and show that my client was engaged in relevant research. Needless to say, a startup's research data and plans are sensitive information.

25. So, I tried to find information regarding other cases where ALJs had entered administrative protective orders to protect such information. I had difficulty locating actual precedent protective orders, however, because prior DEA proceedings and records from those proceeding are not practically available. I ended up filing a motion for an administrative protective order on April 28, 2022, making oblique references to decisions in the Federal Register that indirectly referenced protective orders. The next day, the ALJ denied the motion, asserting in substance that the tribunal lacked authority to enter protective orders. *But see* 21 C.F.R. § 1316.52 (giving presiding officer the power "to take all necessary action to avoid delay, and to maintain order" and "all powers necessary to these ends").

Efforts to Seek Information Relating to Other Matters

26. Apart from my work as an advocate before the agency, I also have made several FOIA requests in support of my journalistic pursuits.

27. As I explained in my February 2023 declaration, for example, in June 2022, I made a request for "[a]ll records related to DEA's formation or structuring of a psychedelic sacramental use advisory council under the Federal Advisory Committee Act; and all records related to the promulgation of formal rules to govern applying for exemptions to the CSA under [the Religious

Freedom for Restoration Act." The agency denied my request for expedited treatment, Ex. 3, and per the "unusual circumstances policy," the request has since been relegated to the backburner.[4]

28. On February 14, 2023, I requested communications between DEA and FDA regarding Adderall shortages described in 87 Fed. Reg. 74168 (Date range for search: January 1, 2022 to February 14, 2023). I requested expedited treatment because I am trying to write an article on the Adderall shortage and seek information regarding quotas. DEA agreed, as reflected in Ex. 4 where it granted my request for expedited treatment. But it is unclear whether DEA expedited anything. Days after DEA agreed that there is "an urgency to inform the public about an actual or alleged federal government activity," DEA informed me that my request raised "unusual circumstances" and extended the time limit indefinitely. Almost 5 months later, despite granting expedited treatment to my request, I have not received any records from DEA, nor have I received a response to my request.

29. I have also sought records from administrative proceeding records. On June 8, 2023, I filed a FOIA request (23-00733-F) for "All records that have been previously produced under FOIA in response to a FOIA request regarding the Morris & Dickson administrative proceedings." DEA searched its case management system and was unable to locate any responsive records pertaining to the subject of my request.

30. On June 27, 2023, I filed a FOIA request (23-00797-F) for "A copy of the August 29, 2019, ALJ Recommended Decision described at 88 Fed. Reg. 34523; and a copy of the transcript of the May 13 to 16, 2019 proceedings described at 88 Fed. Reg. 34523."

31. I requested expedited treatment for Request No. 23-00797-F under the second standard, "an urgency to inform the public about an actual or alleged federal government activity" and the request was "made by a person who is primarily engaged in disseminating information." DEA denied my request for expedited treatment on grounds that I did not show "an urgency to inform the public about an actual or alleged federal government activity."

32. Days later, DEA's Number 2 (Milione) official resigned.[5] In the article "Revolving Door: DEA's No. 2 quits amid reports of previous consulting work for Big Pharma" published on July 19, 2023, the AP writes that "[he] left the DEA again in late June just four days after AP sought comment from the Justice Department about his prior work for Purdue."[6] The article references his work for Morris & Dickson in the proceeding.

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[4] I explained in my February 2023 declaration why DEA's failure to put forward rules for religious freedom exemptions and the records I seek are important and troubling. The issue is best saved for another day because it is not immediately relevant to the issues before the Court.

[5] *See* https://web.archive.org/web/20230701043350/https://www.dea.gov/about/dea-leadership.

[6] *See* https://apnews.com/article/opioids-oxycontin-fentanyl-purdue-pharma-dea-72726613cd30be246905fe1f171c2ed8

33. I also requested expedited treatment under the fourth standard, noting that my request concerned "a matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence." DEA denied my request for expedited treatment under the second standard and per regulations, routed a determination under the fourth standard to DOJ's Director of Public Affairs.[7]

34. I believe DEA's conduct with respect to the Morris & Dickson matter speaks for itself and that my request for proceeding records has not been handled in good faith.

35. As it happens, I have a copy of the ALJ's decision, a true and correct copy of which is attached as Ex. 5, although I am not aware of it being publicly available before its filing in the Fifth Circuit case. I did not leak it to AP or anyone else, and I have no relevant knowledge about the alleged leak. As stated above, the FOIA Office did not produce records to me showing that it has been previously made available under FOIA. Indeed, it appears it was DEA FOIA policy *not* to make the quintessentially public record available.

36. Although I have the decision, I don't have a copy of the transcript, which the decision references and cites pervasively.[8] For example, the decision cites the transcript where the Government raised an ethics/conflict-of-interest issue in its cross-examination of Milione but does not discuss the matter in any level of detail. The transcript provides important context to the information discussed in the decision. It also details the work Milione did for DEA in conjunction with Morris & Dickson before leaving the agency in 2017, and the consulting he did for Morris & Dickson immediately after he left.

37. That Milione left the public sector and began working for regulated entities (a well-trodden path) is unremarkable. It does not give me pause. Indeed, quite the opposite. That an individual with Milione's background and deep experience began assisting companies with compliance issues gives me comfort.

38. The issue that bothers and harms me is the *secrecy*. Separate and apart from the other FOIA issues I have identified, absent national security interests or matters that purely pertain to an individual (e.g., immigration or social security proceedings) or the like, agency proceedings and records from those proceedings should be accessible. Treating a four-year old "administrative file ***as FOIA exempt*** until after issuance of a final order," as is stated in Ex. 6, the Walden Declaration (*Morris & Dickson Co., LLC v. DEA*, Case No. 23-60284, Dkt. 9 at 60 (5th Cir.) beggars belief. And it confirms my concerns about the ongoing First Amendment violations and the unlawfulness of DEA's conduct. I have never heard of a FOIA exemption for pending enforcement proceedings. What federal agencies do, especially in pending enforcement proceedings, is presumptively the public's business and essential to accountability/oversight,

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[7] I note that more than 10 working days have elapsed since my request was routed to the DOJ's Director of Public Affairs, and I have not received a response. *But see* 28 C.F.R. § 16.5(e)(1)(iii) (2022) (time for making an expedited determination is 10 days from receipt).

[8] The current *Morris & Dickson* case discloses a few pages of the transcript at Dkt. 10.

whether in the press or Congress. Neither the public nor Congress can know if a system is functioning—or not—if it operates outside of public view.

39. All this is particularly true of DEA, which is charged with preventing the illegal trafficking of controlled substances that Congress has deemed has "a substantial and detrimental effect on the health and general welfare of the American people," 21 U.S.C. § 802(2). Presumably, when DEA initiates an administrative proceeding, the matter relates to the "health and general welfare of the American people."

40. The failure of the agency to make its precedents and case records public also results in structural injustice to the detriment of the regulated public. The agency, having litigated these matters, has access to these records. Litigants and their attorneys do not.

41. When an agency makes proceedings and precedents unavailable to litigants and advocates, makes arbitrary rulings, can overrule the presiding ALJ at will, interferes with ALJ proceedings—***and*** can also shield those proceedings from public access, scrutiny, and oversight to boot—the First Amendment and the rule of law become dead letters.

42. The docket from the Morris & Dickson case, the ALJ recommended decision, and the transcript of the merits hearings should be publicly accessible today. Records from *all* enforcement proceedings and rulemaking—and particularly those that result in a trial-like hearing involving opioid manufacturers or distributors, as is the case with DEA Docket No. 18-31—should be publicly disclosed or reasonably accessible today. The year is 2023. No agency[9] in the Executive Branch—particularly one in the United States Department of Justice and headed by the Attorney General—should be running a modern-day Star Chamber.

Executed in Harris County, Texas on July 26, 2023.

/s/ Matthew C. Zorn
Matthew C. Zorn

[9] Yes, DEA is an agency. *See* Dkt. 28.

Exhibit 1

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

STATUS CONFERENCE

IN THE MATTER OF:	:	
	:	**Docket No.**
Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT	:	**22-15**

Monday,
July 11, 2022

Videoconference

The above-entitled matter came on for hearing, pursuant to notice, at 1:00 p.m.

BEFORE: THE HONORABLE TERESA A. WALLBAUM,
Administrative Law Judge

APPEARANCES:

On Behalf of the Government:

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PAUL DEAN, ESQ.
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ALSO PRESENT:
ANNE COTTER, Law Clerk to Judge Wallbaum

P-R-O-C-E-E-D-I-N-G-S

1:01 p.m.

JUDGE WALLBAUM: This is an on the record status conference in the matter of scheduling of five tryptamines, Docket No. 22-15. I am the assigned Administrative Law Judge, Teresa A. Wallbaum. Could I have appearances from the government please?

MR. LOCHER: Yes, Your Honor. David Locher for the government.

MR. DEAN: Paul Dean for the government.

MR. WINKLER: And Andrew Winkler for the government.

JUDGE WALLBAUM: All right, thank you. For Mindstate and Tactogen?

MR. ZORN: Matthew Zorn of Yetter Coleman LLP.

JUDGE WALLBAUM: For Wallach and Morris?

MR. HUNTER: John Hunter with Hunter, Lane and Jampala.

JUDGE WALLBAUM: And for Panacea?

MR. HELDRETH: David Heldreth, acting as pro se.

JUDGE WALLBAUM: Thank you. So yes, Mr. Heldreth is the CEO of Panacea, and he is appearing pro se for the company. And just so the record is clear, Mr. Dean, thank you for appearing. I specifically asked for someone, a supervisor for DEA to appear, and I appreciate you making the time to do that.

The purpose of this on the record status conference is narrow. On June 30th, 2022, I had an off the record status conference, and off the record status conferences are relatively common in these proceedings especially at this stage. At that status conference, I expressed my frustration with the government's failure to follow two of my orders.

An order for the disclosure of materials, including noticed exhibits, and an order regarding the publication of the hearing date in this matter. So first for you Mr. Dean, I know that Mr. Beerbower was the lead counsel is no longer with DEA, which is one of the reasons I asked you be here today.

I think I was clear in the off the record status conference and Mr. Walker and Mr. Winkler were there, but I am -- I wanted to

reiterate my frustration that the government has failed to comply with two of my orders so far, and in particular with the disclosure motion. As I said on June 30th, the government had four months to prepare, and I made it very clear they should be prepared. They had four months to prepare the documents.

It was a finite universe of documents, and I made it clear given my generous amount of time up front, I was not inclined to grant extensions. Again, despite all of that, when it came time for the document swap, the government was not ready and failed to produce a number of studies that the interested parties had been asking for for some time.

And on -- and then it became apparent that through email exchanges with the interested parties, Mr. Beerbower offered to negotiate an extension of time, but I had expressly told him I would not grant that. So I know that is -- Mr. Locher and Mr. Winkler were not lead counsel or were not even on the case for most of that.

So I just wanted to reiterate for the record what happened in that -- regarding that order, and so there was no reason for it to

become so complicated, and Mr. Beerbower's responsibility and explain that it was negligence, that he had failed to check the email and the CD for those documents, and I accept that. But they really had plenty of time to avoid that mistake.

So I hope going forward I won't have that mistake again. So that's the, that's the first order.

The second one, and I think the more pressing one from my perspective is the order to publish my -- the date of hearing, and this case has been pending since mid-January or February 1st or February 2nd I believe I when I issued the first OPHS. So there's been a lot of procedural history. Just for your sake and for the record, I'll give a little of that procedural history.

On April 22nd of 2022, the government filed a consent motion to amend the prehearing schedule, claiming that the Notice of Proposed Rulemaking did not include a specific date and time for the hearing in this matter to commence, pursuant to 21 C.F.R. Section 1308.43, paragraph (f). The government indicated that it was working diligently to prepare a Notice of

Hearing, but it requested that this tribunal vacate the prehearing deadlines to allow for publication of that notice.

That was April 22nd. On April 26th, I held a status conference and discussed it with Mr. Beerbower, and explained to him during that status conference that I believe that I could just, if necessary, order the publication of a hearing date which was, as I'm sure you know Mr. Dean, the way it used to always be done until relatively recently, in which now that is waived in one of my prehearing orders.

On April 27th, I issued an order denying the government's consent motion and in that order I noted what I had said at the status conference, which is once the merits hearing date was set, I could if necessary direct the government to publish a notice of that hearing date in the Federal Register to resolve the publication issue. That was April 27th.

On June 7th, I held a prehearing conference. At that time, six weeks after the April 27th status conference, DEA had not published any Notice of Hearing, and we also had not heard any dates or any information from the

government about what was going on. Except there was one time I believe I asked my clerk to reach out via email and was told that there had -- it had not been published.

At the June 7th prehearing conference, Mr. Beerbower did not inform me of any progress on the matter. So on June 13th, I issued an order directing the government to publish my language forthwith. DEA did not file an interlocutory appeal of that order or indicate in any way that it disagreed with my language that I ordered published. So that's the background.

I called the June 30th status conference to address the disclosure issue, but it had been two weeks since I had issued the order to publish the Notice of Hearing and not heard anything, so I asked Mr. Beerbower what the status was, and why specifically the government had not published my order.

Mr. Beerbower stated that he had been instructed by the -- that the Administrator wanted her order published first, and he made clear that he meant the language DEA had suggested in the April 26th status conference. He said that he had been working on that language

ever since. It had gone through separate iterations and versions, and that he had worked the previous weekend to try to get it on the Administrator's desk.

I asked him who had instructed him not to comply with my order, and he said it was his understanding that the instruction had come directly from the Administrator. He repeated that, and the second time he said "the Administrator's Office," and that's my notes, and Mr. Locher, you looked up if you disagree with my representation. But that's what my notes say, that is what my Clerk's notes say and I had the same reaction as what you just had, which was surprise.

He said the Administrator -- his understanding was that it came from the Administrator's office or the Administrator, and that the direction was the April 26th language was supposed to be published first, and then I asked well what about my order, and he said if I still wanted to after then, after that, I could also publish my order.

And that is the main reason we're here today, and Mr. Locher, do you dispute that that

what was said by Mr. Beerbower at --

(Simultaneous speaking.)

MR. LOCHER: I did not mean to look up with either surprise or to disagree. That does more or less accord with my recollection.

JUDGE WALLBAUM: Okay, thank you. I'm sorry. I don't mean to impute anything to you, but I just wanted to give the government a chance to disagree with my recollection if you wanted to. So I find that representation troubling, because the government did not file an interlocutory appeal of my order, and that's the proper mechanism if you want the Administrator to overturn something that I have ordered.

And again, I don't think there's any -- there was no lack of clarity in what Mr. Beerbower said. At a minimum, somebody from the Administrator's office, if not the Administrator herself, instructed CCD to take a certain course of action in regard to a pending order. So again, I know Mr. Beerbower is no longer with DEA, but I wanted to do this on the record, and Mr. Dean, I would like --

As the supervisor from CCD, I was hoping that you could explain to me what happened

in terms of why DEA did not comply with my order to publish my language, went with prior language that I had every understanding was dead in the water, and that you did so with some involvement from the Administrator's office. Could you explain, please expand on that?

MR. DEAN: Good afternoon, Your Honor. I will try. I think I will somewhat limited in what I can say because of attorney-client privilege and just internal agency deliberations. But what I can say is that the agency believes it has substantially complied with your order. While not the identical language, the fact of the matter is almost everything in your order has been published by the agency as of last week.

So I'll stop there, and then if you would like to ask me specific questions, I will attempt to answer them.

JUDGE WALLBAUM: Did Administrator Milgram call CCD directly and give an instruction to disregard my order, which was Mr. Beerbower's representation?

MR. DEAN: Excuse me a moment, Your Honor. I'm trying to make sure that anything I'm saying is not privileged. I don't know exactly -

- I have no reason to dispute your characterization of what Mr. Beerbower said. I don't know that the Administrator herself called Mr. Beerbower. The agency certainly expressed its view that the notice already in process should be done first.

JUDGE WALLBAUM: When you say the -- who expressed their view that the April, I'm going to call it the April 26th language, that that language was in process and should be completed. Who took that view or who expressed that view?

MR. DEAN: Your Honor, I'm not sure if I can give you individual names. I can say that the front office generally expressed that view. But in terms of specific individuals, I am not sure that I am at liberty to name names.

JUDGE WALLBAUM: Can you elaborate on what you mean by "the front office"?

MR. DEAN: By the front office, I mean the agency leadership, including the Administrator, and my not -- so let me be clear. So above Chief Counsel, we'll put it that way.

JUDGE WALLBAUM: I just want to be clear when you -- that that position of the front

office was never in any way communicated to this tribunal, either in an order or any of the staff conferences or prehearing conferences, prehearing conference singular that I held, and I had a pending order.

I understand the position that you said complied substantially with that order, but it's also clear to me from Mr. Beerbower's representations and your representations that you weren't actually complying with my order. You were complying with an April 26th version that was not -- setting aside whether or not it complies with my order, that was not what was going on. You were complying, it sounds like, to a different order, a different directive.

MR. DEAN: Your Honor, I respectfully disagree. I think, and maybe I've misspoken or not spoken clearly enough. The agency's position is that they were complying with your order substantially by the notice that they published, which is substantially similar to your order. Obviously, for example, your order is not formatted these scheduling orders are usually formatted and things of that nature.

The agency's position is that it

substantially complied with your order because the points in your order were published in the Federal Register.

JUDGE WALLBAUM: All right. Well setting that aside, your representation just now, which is consistent with Mr. Beerbower's representation, was your position -- it was the agency's position that the April 26th language should be the one that was put in effect, and my reason for this hearing today is that first of all, no one communicated that to me, which is unacceptable.

Secondly, there was no interlocutory appeal, and third, there seems to be annulment from the Administrator's office in a pending order without an interlocutory appeal. Do you see the reason for my concern with that?

MR. DEAN: Absolutely, Your Honor. I can't speak -- sorry.

JUDGE WALLBAUM: No please, go ahead.

MR. DEAN: I can't speak to necessarily why you weren't notified. I keep repeating the same thing and I apologize for that, but I certainly understand your concerns, and I understand why you would be concerned. I

can just let you know that the agency believes that it has substantially complied with your order.

JUDGE WALLBAUM: And I understand that you're grappling with attorney-client privilege and deliberative process. I'm grappling with the APA, which requires me to give the interested parties a fair hearing, and I'm grappling with the regulations which say that if the government doesn't or any party doesn't agree with my pending order, you need to take an interlocutory appeal.

You don't get to do an ex parte communication with the Administrator about a pending order, and I don't know how to go forward from that if you can't tell me, if you can't give me any more information.

MR. DEAN: I don't believe I can give you any further information without conferring with chief counsel, but I think I can say that I did not mean to suggest and I'm not suggesting that the Administrator herself did something here. I thought I made it clear that it was the front office, and that's a collection of individuals who lead the agency.

There is, as you're well aware, there are individuals in the front office who are partitioned off, so that there are no conflicts of interest matters in active matters that are pending. If Your Honor wanted to do some sort of in camera discussion, we could perhaps go into further detail. But I would again have to speak with either deputy chief counsel and chief counsel.

JUDGE WALLBAUM: Well again, my notes say that Mr. Beerbower said two things. First, he said Administrator. Then he said Administrator's office. He didn't say front office. He didn't say people surrounding the Administrator, and I understand that DEA is large institution and there are people that are cut off.

But can you make a representation today that whoever instructed you to not -- to do, take a different path than my order is not, I don't know. I think you have to make a more detailed representation, that they are not going to be an ultimate decision-maker in this case, or involved in the decision-making in this case.

MR. DEAN: Yeah. I believe I can

represent that, Your Honor.

JUDGE WALLBAUM: So the -- you cannot tell me who instructed you to go forward with the April 26th language, or you will not?

MR. DEAN: I would have to confer with deputy chief counsel and chief counsel as to whether I could give you a name on the record, Your Honor.

JUDGE WALLBAUM: But is your representation that that person is not -- will not be involved in this case after a recommended decision is issued in determining the agency's final ruling on the matter. Can you make that representation?

MR. DEAN: I believe that I can, Your Honor, if I'm understanding your question correctly. I believe that I can, and if I find out something different, I'll of course notify the Court immediately. But I am comfortable making that representation.

JUDGE WALLBAUM: So again Mr. Dean, just so you understand why we're here today, I don't know what happened. The parties, the interested parties don't know what happened. There was a representation that the Administrator

or the Administrator's office was involved, and outside of the regulatory proceedings, procedures.

So I have to be able to provide a fair hearing, and if the person who's giving you these directions is involved in the decision-making process, then I think that raises a separate issue. So that's why I'm asking for a clear representation from the government that whoever gave you the instruction to do the different language is not going to be involved in reviewing my recommended decision. Do you understand that?

MR. DEAN: I do understand it, Your Honor, and I believe that's the case. I don't know all the individuals involved, but I do believe that's the case. That's why I said I'm willing to make that representation. If I find out that I am wrong, I will let you know immediately.

JUDGE WALLBAUM: Right, and can the government also make a representation that if anyone from the front office gives you instructions to do something differently than what I've offered, that you inform the tribunal of that?

MR. DEAN: I think we -- I think I can. I don't --

JUDGE WALLBAUM: I need more than I think I can. I need more than I think I can Mr. Dean, because at a bare minimum going forward, I have to know that the hearing is -- that everything that's happening is happening in this hearing proceeding and not in ex parte communications.

MR. DEAN: Of course Your Honor, yes, yes. I understand that and yes. We can make a representation.

JUDGE WALLBAUM: You can make a representation that if there's another direction to do something differently than what my order has said, that will be communicated to this tribunal promptly before, so that I can inform the interested parties?

MR. DEAN: Yes, Your Honor.

JUDGE WALLBAUM: I'm going to hold you to that. I'm going to hold the government to those representations. I'm also going to note that in the published Federal Register Notice of Hearing, which is 87 -- it's 87 Federal Register 40167, there are two errors in your published

notice. The first is you have an incorrect phone number.

The phone number 571-362-8188 is not the phone number associated with the Office of Administrative Law Judges. It is, as far as I can tell, an employee of DEA who has nothing to do with us or with you. So you might want to sort that out, because that employee may get phone calls and not know what to do with them.

The second thing, and this is more for the interested parties, I have not set a location. It says Crystal City, which is currently where we are located. But it may happen in nearby, a few blocks away at DEA headquarters. That I will give everyone advance on, but it's very close and so shouldn't -- if we change places, it shouldn't be any inconvenience, and the regulations do allow me to change the location of the hearing without having to give additional notice. We would just make sure that if anyone showed here at Crystal City, they would know where the proper place was to go. Just a moment please.

(Pause.)

JUDGE WALLBAUM: All right. That's

all I have for the on the record hearing. Mr. Dean, if there's anything else that the government can represent to me about what happened you may -- please do so. I am taking away a couple of representations from you, and as I said, I'm going to hold the government to it or I'm going to consider the appropriate sanctions for failure to do that.

So if there -- is there anything else from the government about the topics I've discussed on the record?

MR. DEAN: I have nothing further, Your Honor.

MR. LOCHER: None, Your Honor.

JUDGE WALLBAUM: All right. Mr. Zorn, anything that I've discussed on the record, do you have any comments or questions.

MR. ZORN: Just two very short comments. The first is your recollection is the same as mine. I was at the informal status conference and I recall and he stated as you stated it. The second point is I heard the government invoking privilege. I personally question whether privilege can be invoked by a waiver on the record.

We've had an off the record status conference, because again he offered -- Mr. Beerbower disclosed the substance of communications with the Administrator's office. The second point is I'm not sure that privilege can be invoked when it's being used to disregard a court order. I don't think the attorney-client privilege protects those kinds of communications.

I have other matters, but they don't relate to this topic. So I understand Your Honor's purpose and the on the record status conference, and I will save it until we get off the record.

JUDGE WALLBAUM: Thank you. Mr. Hunter, any other questions or comments from you about the topic I discussed on the record?

MR. HUNTER: Yes Your Honor, briefly. I agree with Mr. Zorn and with Your Honor as to the factual representations regarding what Mr. Beerbower at our informal conference. I heard the remarks the same as Your Honor and Mr. Zorn did. I also agree that what this case seems to present is an instance of waiver, that Mr. Beerbower directly relayed the substance of the conversation that he had, and therefore the

communication itself and the attending circumstances of that communication I don't think are any longer covered by privilege.

I also expressed, I share the Court's concern about this because especially given the nature of these proceedings and the relationship between Your Honor, the Administrator and the agency itself, we have a fairly closed loop that does not seem to provide an individual due process safeguard for a problem like this, in that the -- it appears that an ex parte communication was had, and that ex parte communication substance was to disregard an order from Your Honor.

The agency is now claiming a privilege that prevents the parties from being able to test and understand the depths and extent of that violation, and to the extent that any relief is sought to rectify that problem, the party that will receive the interlocutory appellate relief on that question is the very party from whom this ex parte communication was established.

And that seems to provide very little independent review of whether an impropriety has occurred here or not. As Your Honor has pointed

out, neither you nor the parties understand what this was about, why it happened the way it did, etcetera.

So those are my concerns, and based on those concerns I would ask if the Court can make a ruling about the claim of privilege that the agency has raised today, and I would ask that the Court overrule that claim of privilege and direct the agency to provide the content of the communication, and identify the individuals who gave them these instructions.

JUDGE WALLBAUM: All right, thank you Mr. Hunter. Do you have anything else?

MR. HUNTER: No Your Honor, that's it.

JUDGE WALLBAUM: Thank you. Mr. Heldreth. Anything about what I discussed this on the record conference?

MR. HELDRETH: Just briefly. I agree with both Hunter and Zorn on this, and also I directly heard the Administrator and the Administrator's office mentioned by the DEA as the people who were responsible for making decisions. As I've said in previous motions that I've had, I also believe there's a deep, deep problem with the communication here, which shows

that there cannot be a fair hearing.

And based on this, we again are appealing with the interlocutory appeals and plan filing an appeal on the previous one with the DEA, that the Administrator made. So we just want to put that on record, that we can go to the Appeals court on these issues, and agree that we want the privilege motion or ruling to be made. So thank you.

JUDGE WALLBAUM: Thank you. Mr. Dean, what about the argument that Mr. Beerbower waived any privilege on the government's behalf when he disclosed twice that there had been this communication? Don't you at a minimum have to tell me who you communicated with? How is who you communicated with covered by privilege even if it did exist?

MR. DEAN: Well Your Honor, I guess there's a couple of things to unpack here. Whether Mr. Beerbower spoke inelegantly and said the Administrator or even if the Administrator's office is accepting it, we can't really get to despite recollections because we don't have a transcript and I was not there at the hearing.

JUDGE WALLBAUM: Everybody's in

agreement as to what was said, even Mr. Locher, who was there. So I -- we proceed all the time with off the record status conferences, and all of the time we hold the parties, including respondents, to state -- things that were said during off the -- status conferences where there was not a court reporter.

So that seems to be a well-established process, that things said at a status conference can be referenced subsequently in orders in these proceedings.

MR. DEAN: Your Honor, yeah. That's not what I was saying. But my point was if he referenced both the Administrator and the Administrator's office, we don't know what he meant. I mean we can guess at what he's saying. I think he spoke inelegantly. I think he meant the Administrator's office. I think my references to the front office have been fairly clear. I made representations to you which should allay many of the concerns that have been raised here.

JUDGE WALLBAUM: Well, Administrator's office includes the Administrator, and whether that was elegant or inelegant, it still raises a

question that there have been communication with people administrator-adjacent, as to these proceedings.

(Simultaneous speaking.)

MR. DEAN: I think --

JUDGE WALLBAUM: I'm sorry?

MR. DEAN: I'm sorry, Your Honor. I thought you were finished.

JUDGE WALLBAUM: I am, go ahead, thanks.

MR. DEAN: I thought I had explained previously that there are procedures in place so that all those involved in issuing final decisions, final orders are not the same people who are contacted or had input into these matters while they're active in litigation. So my apologies to the extent that it wasn't clear, but I thought I had made that point previously.

JUDGE WALLBAUM: What about the argument that Mr. Beerbower waived any privilege when he made that representation as to who he had communicated with?

MR. DEAN: I think that would be a fairly wrong assertion, because I am stating now that -- and I stated to you previously that the

Administrator was not involved in that. I believe that's what I had said, and I also said that they had separate individuals being involved regardless, from the front office involved in reviewing this.

So to the extent that perhaps I'm -- I understand the gravity of the situation and Your Honor's interest in making sure there's a fair hearing, but I don't think that the fact that Mr. Beerbower may have erroneously said Administrator or Administrator's office when he was referring to a collective group of individuals, which I've been referring to as the front office, waives any sort of privilege.

The agency may decide to disclose this information to you, I don't know. But they may not, and I think the agency's position at this point is that it's internal deliberation, and you have -- you have the agency's position, which is evidenced in the scheduling notice that was published, and my assurances to you on the record that we've made throughout this hearing today.

JUDGE WALLBAUM: Mr. Dean, how does deliberative process or attorney-client privilege or work product, whichever privilege you want to

rely on, how does that protect the name of the person who gave you the instruction? That's not a content of the conversation. That's merely a title or a name. How is that covered by privilege?

MR. DEAN: Well first of all Your Honor, I don't know specifically who it was, but more generally I -- so I can't help you there. But more generally, I think any sort of individuals within the agency who are involved in any sort of decision-making would not, would not have to be named.

JUDGE WALLBAUM: You said earlier the agency would have to decide whether or not to provide that information. Is that still a possibility, that the government could decide to disclose that information in these proceedings, as to who specifically provided that instruction?

MR. DEAN: I would have to speak with the deputy chief counsel and chief counsel, to see whether they would be willing to do that, or the agency is willing to do that. I mentioned it, so it is a possibility. Unfortunately, I can't tell you more than that at this point.

JUDGE WALLBAUM: All right. Well I'll

let the government consider whether it wants to do that, and wants to disclose anything else. Obviously I have an obligation to provide a fair hearing to the parties in this case.

I take that very seriously, and I've heard your representation. But this will not happen again without me being informed of it, although if we come to the point again where me being informed of it doesn't let me know who is doing it, that may pose some of the same issues that we have here right now.

But I'll close with saying that that's something the government can discuss internally, as to whether it wants to disclose additional information on this matter, or not. There obviously certain consequences associated with not. Anything else, Mr. Dean?

MR. DEAN: No, Your Honor.

JUDGE WALLBAUM: All right, all right. Thank you all very much.

MR. ZORN: May I just add something quickly for the record?

JUDGE WALLBAUM: Yes, Mr. Zorn.

MR. ZORN: There's one thing that the government said that actually bothers me, which

is they're for walling off certain people.

JUDGE WALLBAUM: I'm sorry Mr. Zorn, if I could stop you right there. That last portion was very garbled, so you might want to restate it.

MR. ZORN: My apologies. Let me get closer. The government said one thing that bothered me, which was there's a procedure for walling off certain people. The decision in this case is made by the Administrator and to the extent others are assisting her, or sorry the final, obviously Your Honor makes the recommendation.

To the extent there's any authority for others to be involved, it is a delegation from the Administrator. So this is not like a situation in private practice where you have multiple partners in a law firm and you can wall them off from each other. This all goes to the same decision-maker, and I think whoever was involved in this decision, and this is also again why who is involved actually matters, but whoever was involved in this took a delegation from the Administrator, and whoever is going to review the final decision is delegated, whether it's the

Administrator herself or not.

But legally it has to be the Administrator herself. So I don't think this walling off process, to the extent there is prejudice or bias and, you know, against the interested party including my party has already made that allegation. We cited Overton Park in our papers. I'm not going to rehash old ground, but that is not a procedure proposed by the government, which I think has any legal basis whatsoever. It all comes from the Administrator.

And then the other point I would note is, and I understand Your Honor's order denying our request for disclosure. I'm not here to rehash that, but I have separately made FOIA requests for judicial records. I would like the carisoprodol proceedings. It's the only precedent of recent memory. The agency is not turning that over. I don't understand the walls of secrecy that are involved in this, why you can't get simple discovery from the agency.

But to me, this is kind of a troublesome practice here of we can't seem to get information, and the reason that relates to what we're talking about is this was a notice of

hearing to allow the public to participate in these proceedings. I don't understand how or why it took them so long to do it. I'm not here to rehash that, but I just don't want that to be lost, as to why this was an important order that Your Honor put out.

JUDGE WALLBAUM: Thank you Mr. Zorn, and thank you Mr. Hunter and Mr. Heldreth. So that for me concludes the on the record portion.

I know Mr. Zorn and perhaps others wanted to address a few things, procedural matters off the record. I will note that I will receive a transcript of this hearing, of this sorry, this status conference and I will distribute that to the parties promptly upon my receipt of that.

So if that's all, then we can at this stage go off the record. Thank you.

(Whereupon, the above-entitled matter went off the record at 1:57 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Scheduling of Five Tryptamines Status Conference

Before: DEA

Date: 07-11-22

Place: teleconference

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate complete record of the proceedings.

Neal R. Gross

Court Reporter

Exhibit 2

U.S. Department of Justice
Drug Enforcement Administration
FOIA and Privacy Act Unit
8701 Morrissette Drive
Springfield, Virginia 22152

September 16, 2022

Case Number: 22-00560-F

Subject: All filings from the proceedings in Administrative Law Judge (ALJ) Docket No. 10-46 described in 76 Fed. Reg. 77329 (Docket No. DEA-333), including briefs filed and all ALJ orders, such as the ALJ decision (Date Range for Record Search: January 13, 2015 to January 13, 2011)

Matthew Zorn, Esq.
Yetter Coleman LLP
811 Main Street, Suite 4100
Houston, Texas 77002
Sent via e-mail: mzorn@yettercoleman.com

Dear Mr. Zorn:

This letter responds to your Freedom of Information Act/Privacy Act (FOIA/PA) request dated April 22, 2022, addressed to the Drug Enforcement Administration (DEA), FOIA/PA Unit, seeking access to information regarding the above subject.

After reviewing your request, we conducted a search for records responsive to the above noted subject. To search for responsive records we queried the Office of the Administrative Law Judges. The search has been completed.

We have determined that you are making this request for a "commercial use" as described in Department of Justice regulation, 28 C.F.R. § 16.10(b)(1). As such, we are required to assess fees for review of responsive records. *See id.* at § 16.10(c). You may review the Department of Justice regulations which establish the fees charged for processing FOIA requests at: https://www.ecfr.gov/current/title-28/chapter-I/part-16.

Review fees by professional personnel are charged at $40.00 per hour. *See* 28 C.F.R. § 16.10(c)(1)(ii) and (c)(3). This fee is assessed for review time required by both supervisory and non-supervisory personnel. Review time includes processing of any records for disclosure, including redacting the records and asserting the appropriate FOIA exemptions. We charge review fees even if we ultimately are unable to disclose records to you. Accordingly, we estimate the review time associated with your request will total $41,960. Please note, this office is unable to continue with the processing of your request until you agree to pay the fee.

As provided by 28 C.F.R § 16.3(b), this letter also affords you the opportunity to reformulate your request in such a manner as to reduce the review fee. This could be accomplished by narrowing scope of your request or specifying particular documents that you desire.

Upon receipt of a **check or money order** in the amount indicated above, made payable to the Treasury of the United States, DEA will initiate further processing of your request. Please indicate the case number noted above on the face of your check or money order, and mail it to the above address. However, if this office does not receive your payment within 30 business days, DEA will assume that you do not wish to pursue this matter and your request will be administratively closed. If this office administratively closes your request, you may submit a new request at any time.

You may contact our FOIA Public Liaison at (571) 776-2300 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, Room 2510, 8601 Adelphi Road, College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at (202) 741-5770; toll free at 1-877-684-6448; or facsimile at (202) 741-5769.

If you are not satisfied with DEA's determination in response to this request, you may administratively appeal by writing to the Director, Office of Information Policy (OIP), United States Department of Justice, 441 G Street, NW, 6th Floor, Washington, D.C. 20530, or you may submit an appeal through OIP's FOIA STAR portal by creating an account following the instructions on OIP's website: https://www.justice.gov/oip/submit-and-track-request-or-appeal. Your appeal must be postmarked or electronically transmitted within 90 days of the date of my response to your request. If you submit your appeal by mail, both the letter and the envelope should be clearly marked "Freedom of Information Act Appeal."

If you have any questions regarding this letter, you may contact FOIA/PA Unit representative Rickey L. Polk, Jr. at (571) 776-3325 or via e-mail at Rickey.L.PolkJr@dea.gov.

Sincerely,

KELLEIGH MILLER Digitally signed by KELLEIGH MILLER
Date: 2022.09.16 10:54:59 -04'00'

Kelleigh A. Miller, Chief
Freedom of Information and Privacy Act Unit
Administrative and General Law Section
Office of Chief Counsel

Exhibit 3

U.S. Department of Justice
Drug Enforcement Administration
FOIA and Privacy Act Unit
8701 Morrissette Drive
Springfield, Virginia 22152

June 30, 2022

Case Number: 22-00806-F

Subject: All records related to DEA's formation or structuring of a psychedelic sacramental use advisory council under the Federal Advisory Committee Act; and all records related to the promulgation of formal rules to govern applying for exemptions to the CSA under RFRA
(Date Range for Record Search: 1/1/2020 to 6/11/2022)

Matthew Zorn
Partner
Yetter Coleman LLP
811 Main Street, Suite 4100
Houston, Texas 77002
Sent via e-mail: mzorn@yettercoleman.com

Dear Matthew Zorn:

This letter responds to your Freedom of Information Act/Privacy Act (FOIA/PA) request dated June 27, 2022, addressed to the Drug Enforcement Administration (DEA), FOIA/PA Unit, seeking expedited treatment.

In your request letter, you request expedited treatment pursuant to the first, second, third, and/or fourth standards enumerated in the Department of Justice's regulations. Expedited treatment pursuant to the first standard will be granted where not doing so "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual." 5 U.S.C. § 552(a)(6)(E)(v)(I). *See also* 28 C.F.R. § 16.5(e)(1)(i) (2019). Under the second standard, you must show that there is "n urgency to inform the public about an actual or alleged Federal Government activity, if made by a person primarily engaged in disseminating information." 5 U.S.C. § 552(a)(6)(E)(v)(II). *See also* 28 C.F.R. § 16.5(e)(1)(ii) (2019). Under the third standard, you must show that the request involves "he loss of substantial due process rights." 28 C.F.R. § 16.5(e)(1)(iii) (2019). Under the fourth standard, you must show that the subject matter of your request is a "matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence." *Id.* at § 16.5(e)(1)(iv). This office makes determinations regarding the first three standards, while the Department's Director of Public Affairs makes determinations regarding the fourth standard. *See id.* at § 16.5(e)(2).

You have requested expedited processing of your request pursuant to the Department's standard permitting expedition for requests involving "n urgency to inform the public about an actual or alleged federal government activity, if made by a person primarily engaged in disseminating information." 28 C.F.R. § 16.5(e)(1)(ii) (2019). Based on the information you have provided, we have determined that your request for expedited processing under this standard

should be denied. The primary activity of your organization does not appear to be information dissemination, which is required for a requester to qualify for expedited processing under this standard. Please be advised that, although your request for expedited processing has been denied; it has been assigned to a FOIA/PA Unit representative in this office.

If you are not satisfied with DEA's determination in response to this request, you may administratively appeal by writing to the Director, Office of Information Policy (OIP), United States Department of Justice, 441 G Street, NW, 6th Floor, Washington, D.C. 20530, or you may submit an appeal through OIP's FOIA STAR portal by creating an account following the instructions on OIP's website: https://www.justice.gov/oip/submit-and-track-request-or-appeal. Your appeal must be postmarked or electronically transmitted within 90 days of the date of my response to your request. If you submit your appeal by mail, both the letter and the envelope should be clearly marked "Freedom of Information Act Appeal."

If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact FOIA/PA Unit representative Rickey L. Polk, Jr. at (571) 776-3325 or via e-mail at Rickey.L.PolkJr@dea.gov, our FOIA Requester Service Center at (571) 776-2300, e-mail your correspondence to DEA.FOIA@dea.gov, or mail your correspondence to the above address. In addition, you may contact our FOIA Public Liaison at (571) 776-2300 to discuss any aspect of your request.

Sincerely,

YVETTE DAVIS Digitally signed by YVETTE DAVIS
Date: 2022.06.30 08:44:04 -04'00'

Yvette D. Davis, Chief
Intake Sub-Unit
Freedom of Information and Privacy Act Unit

Exhibit 4

U.S. Department of Justice
Drug Enforcement Administration
FOIA and Privacy Act Unit
8701 Morrissette Drive
Springfield, Virginia 22152

February 16, 2023

Case Number: 23-00347-F

Subject: Communications between DEA and FDA regarding Adderall shortages described in 87 Fed. Reg. 74168 (Date range for search: January 1, 2022 to February 14, 2023)

Matthew Zorn, Esq.
Yetter Coleman LLP
811 Main Street Suite 4100
Houston, Texas 77002
Sent via e-mail: mzorn@yettercoleman.com

Dear Mr. Zorn:

This letter responds to your Freedom of Information Act/Privacy Act (FOIA/PA) request dated February 14, 2023, addressed to the Drug Enforcement Administration (DEA), FOIA/PA Unit, seeking expedited treatment.

In your request letter, you seek expedited treatment pursuant to the first, second, third, and/or fourth standards enumerated in the Department of Justice's (DOJ) FOIA regulations. Expedited treatment pursuant to the first standard will be granted where not doing so "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual." 5 U.S.C. § 552(a)(6)(E)(v)(I); *see also* 28 C.F.R. § 16.5(e)(1)(i) (2022). Under the second standard, you must demonstrate that there is "an urgency to inform the public about an actual or alleged [f]ederal [g]overnment activity, if made by a person primarily engaged in disseminating information." 5 U.S.C. § 552(a)(6)(E)(v)(II); *see also* 28 C.F.R. § 16.5(e)(1)(ii) (2022). The third standard requires you to demonstrate that the request involves "[t]he loss of substantial due process rights." 28 C.F.R. § 16.5(e)(1)(iii) (2022). To satisfy the fourth standard, you must demonstrate that the subject matter of your request is "[a] matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence." *Id.* at § 16.5(e)(1)(iv). This office makes determinations regarding the first three standards, while DOJ's Director of Public Affairs makes determinations regarding the fourth standard. *See id.* at § 16.5(e)(2).

Based on the information you have provided, we have granted your request for expedited processing under Standard II. Your FOIA request has been assigned to a representative in this office for further processing. It will be placed in chronological order with other pending expedited treatment requests and will be addressed in turn.

You may contact our FOIA Public Liaison at (571) 776-2300 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, Room 2510, 8601 Adelphi Road, College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at (202) 741-5770; toll free at 1-877-684-6448; or facsimile at (202) 741-5769.

If you have any questions regarding this letter, you may contact FOIA/PA representative George Margaryan at (571) 776-3004 or via e-mail at Gevorg.G.Margaryan@dea.gov. You may also contact our Requester Service Center at DEA.FOIA@dea.gov.

Sincerely,

WANDA JONES Digitally signed by WANDA JONES Date: 2023.02.16 12:22:46 -05'00'

for
Joshua L. Delo, Acting Chief
Intake Sub-Unit
Freedom of Information and Privacy Act Unit

Exhibit 5

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Morris & Dickson, Co., LLC**	**Docket No. 18-31**

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION

Charles Wm. Dorman
U.S. Administrative Law Judge

August 29, 2019

Appearances:

Paul A. Dean, Esq.
John E. Beerbower, Esq.
for the Government

Jodi L. Avergun, Esq.
Keith M. Gerver, Esq.
Joshua P. Arnold, Esq.
for the Respondent

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On May 3, 2018, the Drug Enforcement Administration ("DEA" or "Government") served Morris & Dickson, Co., LLC ("Respondent") with an Order to Show Cause and Immediate Suspension of Registration ("OSC/ISO"), immediately suspending the DEA Certificates of Registration ("COR"), Numbers RM0314790 and RM0335732, of Morris & Dickson Co., LLC ("Respondent"), pursuant to 21 U.S.C. § 824(d), and proposing to revoke its CORs and deny any pending applications for renewal or modification, pursuant to 21 U.S.C. §§ 824(a)(4) and 823(b). Administrative Law Judge Exhibit ("ALJ-") 1; ALJ-2. In response to the OSC/ISO, the Respondent timely requested a hearing before an Administrative Law Judge. ALJ-3. The hearing that the Respondent requested was held in Arlington, Virginia, on May 13-16, 2019.

I note that the Respondent has requested confidential treatment of all of its exhibits, as well as a portion of the testimony of Mr. Kenneth A. Weinstein. Tr. 14-16, 559; ALJ-81-82. That portion of Mr. Weinstein's testimony for which the Respondent requests confidential treatment begins on page 560 and ends on page 689 of the transcript.

The issue before the Acting Administrator is whether the record as a whole establishes by a preponderance of the evidence that the DEA Certificates of Registration of Morris & Dickson, Co., LLC, No. RM0314790, and Morris & Dickson, Co., LLC, d/b/a Spark Drug, Inc., No. RM0335732, should be revoked, and any pending applications be denied, because their continued registrations would be inconsistent with the public interest under 21 U.S.C. §§ 824(a)(4), and 823(b) and (e). ALJ-9, at 1.

This Recommended Decision is based on my consideration of the entire Administrative Record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

THE ALLEGATIONS

1. Morris & Dickson failed to maintain effective controls against diversion in that it failed to report to DEA thousands of unusually large orders for hydrocodone and oxycodone and it shipped those orders without resolving red flags of diversion. ALJ-1, at 2, para. 2.
2. Morris & Dickson failed to maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," in violation of 21 U.S.C. § 823(b)(1) and 21 C.F.R. § 1301.71(a). ALJ-1, at 3, paras. 7, 10.

3. Morris & Dickson failed to adequately "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and report them to DEA, in violation of 21 C.F.R. § 1301.74(b). ALJ-1, at 3, paras. 8, 10.

4. Morris & Dickson ignored and/or failed to implement its due diligence and suspicious order monitoring policies and failed to conduct meaningful due diligence into these orders to ensure that the controlled substances were not diverted into other than legitimate channels. ALJ-1, at 3, para. 10. Morris & Dickson has routinely shipped—and, as recently as February 28, 2018, continues to ship—controlled substances despite evidence suggesting a likelihood of diversion. *Id.*

5. Between January 2014 and September 2017, Morris & Dickson filed a total of three suspicious order reports with DEA. ALJ-1, at 4-5, paras. 12-13, 17. For two reports filed in April 2017, Morris & Dickson shipped the orders for controlled substances before reporting the orders to DEA. *Id.* at 4, para. 13. For the third report filed in April 2014, the report did not contain sufficient information to determine whether Morris & Dickson shipped the order for controlled substances. *Id.*

6. In response to an administrative subpoena served by DEA on February 5, 2018, Morris & Dickson indicated it did not believe that it was required to maintain records on investigations of potentially suspicious orders. ALJ-1, at 4-5, paras. 14, 16. Morris & Dickson's response stated that "formal records are not kept in the regular course of business on the investigation of orders which do not result in the finding of a suspicious order. *Id.* at 5, para. 16. Morris & Dickson did not produce any such records in response to DEA's subpoena. *Id.*

7. Between January 1, 2014 and April 30, 2018, Morris & Dickson shipped 7,252 unusually large orders of oxycodone (12,594,100 dosage units) and 4,948 unusually large orders of hydrocodone (22,042,800 dosage units). ALJ-1, at 5, paras. 18-20; ALJ-52, at 19. Morris & Dickson did not report any of these orders as suspicious to DEA, except for the three reports noted in paragraph 5. ALJ-1, at 5, para. 20. As a result, Morris & Dickson failed to maintain effective controls against the diversion of controlled substances, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1), and 21 C.F.R. § 1301.71(a), and failed to identify and report suspicious orders of controlled substances to DEA, in violation of 21 C.F.R. § 1301.74(b). *Id.* at 5-6, paras. 21-23.

8. Morris & Dickson failed to implement its due diligence and suspicious order monitoring policies and failed to conduct or failed to document the resolution of meaningful due diligence into orders placed by the following seven pharmacies:

a. **Wallace Drug Company, Inc. d/b/a Wallace Discount Drugs ("Wallace"):** Between January 1, 2014 and April 30, 2018, Morris & Dickson shipped 6 orders of hydrocodone (78,000 dosage units) and 1 order of oxycodone (6,000 dosage units) to Wallace that were unusually large. ALJ-1, at 7, para. 30; ALJ-52, at 20. Morris & Dickson shipped controlled substances to Wallace despite being aware of red flags for diversion. Morris & Dickson failed to conduct adequate due diligence sufficient to resolve those red flags and failed to report suspicious orders to DEA. ALJ-1, at 7, paras. 30, 32.

b. **Bordelon's Super-Save Pharmacy ("Bordelon's"):** Between January 1, 2014 and September 2017, Morris & Dickson shipped 359 orders of hydrocodone (430,570 dosage units) and 1,184 orders of oxycodone (458,430 dosage units) to Bordelon's. ALJ-1, at 7, para. 36. Morris & Dickson shipped controlled substances to Bordelon's despite being aware of red flags for diversion. Morris & Dickson failed to conduct adequate due diligence sufficient to resolve those red flags and failed to report suspicious orders to DEA. ALJ-1, at 7, paras. 35, 38-39. Morris & Dickson shipped 50 unusually large orders of oxycodone (83,500 dosage units) to Bordelon's between January 1, 2014 and April 30, 2018, and 2 unusually large orders of hydrocodone (24,000 dosage units) to Bordelon's between January 1, 2014 and April 30, 2018. ALJ-1, at 7, para. 37; ALJ-52, at 20. Among the unusually large orders shipped to Bordelon's were an order for 2,000 dosage units of oxycodone shipped in January 2017 (approximately ten times the median order for Bordelon's); 3,000 dosage units of oxycodone shipped in May 2015 (approximately fifteen times the median order for Bordelon's); and four orders totaling 42,000 dosage units of hydrocodone shipped in September 2014 (approximately forty-two times the median order for Bordelon's). ALJ-1, at 7-8, paras. 37(a)-(c).

c. **Folse Pharmacy ("Folse"):** Morris & Dickson shipped 973 orders of hydrocodone (1,586,630 dosage units) and 2,314 orders of oxycodone (2,270,700 dosage units) to Folse between January 2014 and September 2017. ALJ-1, at 8, para. 45.

Specifically, between January 1, 2014 and April 30, 2018, Morris & Dickson shipped 58 unusually large orders of oxycodone to Folse (337,200 dosage units) and 68 unusually large orders of hydrocodone (624,000 dosage units) to Folse. *Id.* at 8-9, para. 46; ALJ-52, at 20. Morris & Dickson shipped controlled substances to Folse despite being aware of red flags for diversion. Morris & Dickson failed to conduct adequate due diligence sufficient to resolve those red flags and failed to report suspicious orders to DEA. ALJ-1, at 8-9, paras. 44, 47-48. Among the unusually large orders shipped to Folse were two orders totaling 12,000 dosage units of oxycodone shipped in September 2017 (each order approximately twelve times the median order for Folse); two orders totaling 24,000 dosage units of hydrocodone shipped in August 2017 (each order approximately twelve times the median order for Folse); and two orders totaling 14,000 dosage units of oxycodone shipped in September 2015 (each order approximately fourteen times the median order for Folse). ALJ-1, at 8-9, paras. 46(a)-(c).

d. **Pharmacy Specialties Group, Inc. ("Pharmacy Specialties"):** Morris & Dickson shipped 184 orders of hydrocodone (224,330 dosage units) and 464 orders of oxycodone (238,520 dosage units) to Pharmacy Specialties between January 2014 and September 2017. ALJ-1, at 9, para. 53. Specifically, Morris & Dickson shipped to Pharmacy Specialties 10 unusually large orders of oxycodone (23,200 dosage units) between January 1, 2014 and April 30, 2018 and 15 unusually large orders of hydrocodone (68,000 dosage units) between January 1, 2014 and April 30, 2018. ALJ-1, at 9-10, para. 54; ALJ-52, at 20. Among the unusually large orders shipped to Pharmacy Specialties were 2,400 dosage units of oxycodone shipped in October 2016 (approximately five times the median order for Pharmacy Specialties); 12,000 dosage units of hydrocodone shipped in January 2016 (approximately twelve times the median order for Pharmacy Specialties); and 12,000 dosage units of hydrocodone shipped in September 2015 (approximately twelve times the median order for Pharmacy Specialties). ALJ-1, at 9-10, para. 54(a)-(c). Morris & Dickson shipped controlled substances to Pharmacy Specialties despite being aware of red flags for diversion. Morris & Dickson failed to conduct adequate due diligence sufficient to

resolve those red flags and failed to report suspicious orders to DEA. ALJ-1, at 9-10, paras. 52, 55, 58-59.

e. **Dave's Pharmacy ("Dave's"):** Morris & Dickson shipped 1,990 orders of hydrocodone (3,273,280 dosage units) and 4,808 orders of oxycodone (2,029,400 dosage units) to Dave's between January 2014 and September 2017. ALJ-1, at 11, para. 64. Specifically, Morris & Dickson shipped to Dave's 103 unusually large orders of oxycodone (264,200 dosage units) between January 1, 2014 and April 30, 2018, and 14 unusually large orders of hydrocodone (141,000 dosage units) between January 1, 2014 and April 30, 2018. ALJ-1, at 11, para. 65; ALJ-52, at 20. Among the unusually large orders shipped to Dave's were 6,000 dosage units of oxycodone shipped in April 2017 (approximately twenty times the median order for Dave's); three orders of 18,000 total dosage units of oxycodone shipped in June 2015 (each order approximately twenty times the median order for Dave's); and two orders totaling 24,000 dosage units of hydrocodone shipped in March 2015 (each order approximately twelve times the median order for Dave's). ALJ-1, at 11, paras. 65(a)-(c). Morris & Dickson shipped controlled substances to Dave's despite being aware of red flags for diversion. Morris & Dickson failed to conduct adequate due diligence sufficient to resolve those red flags and failed to report suspicious orders to DEA. ALJ-1, at 10-11, paras. 62-63, 66-67.

f. **The Wellness Pharmacy, Inc. ("Wellness"):** Morris & Dickson shipped 4,997 orders of oxycodone (3,083,080 dosage units) and 1,351 orders of hydrocodone (1,569,010 dosage units) to Wellness between January 2014 and September 2017. ALJ-1, at 13, para. 83. Specifically, Morris & Dickson shipped to Wellness 119 unusually large orders of oxycodone (387,800 dosage units) and 3 unusually large orders of hydrocodone (18,000 dosage units) between January 1, 2014 and April 30, 2018. ALJ-1, at 13, para. 84; ALJ-52, at 20. Among the unusually large orders shipped to Wellness were 6,000 dosage units of oxycodone shipped in June 2017 (approximately fifteen times the median order for Wellness); 6,000 dosage units of oxycodone shipped in April 2017 (approximately fifteen times the median order for Wellness); 5,000 dosage units of oxycodone shipped in April 2017 (approximately twelve times the median order for Wellness); and two orders totaling 12,000 dosage

units of hydrocodone shipped in October 2014 (each order approximately six times the median order for Wellness). ALJ-1, at 13, paras. 84(a)-(c). Morris & Dickson shipped controlled substances to Wellness despite being aware of red flags for diversion. Morris & Dickson failed to conduct adequate due diligence sufficient to resolve those red flags and failed to report suspicious orders to DEA. ALJ-1, at 13, paras. 82, 85, 88.

g. **Wilkinson Family Pharmacy ("Wilkinson"):** Morris & Dickson shipped 1,284 orders of hydrocodone (1,431,680 dosage units) and 4,564 orders of oxycodone (3,100,140 dosage units) to Wilkinson between January 2014 and April 2017. ALJ-1, at 14, para. 92. Specifically, Morris & Dickson shipped to Wilkinson 2 unusually large orders of oxycodone (11,000 dosage units) and 49 unusually large orders of hydrocodone (421,000 dosage units) between January 1, 2014 and April 30, 2018. ALJ-1, at 14, para. 93; ALJ-52, at 20. Among the unusually large orders shipped to Wilkinson were 6,000 dosage units of oxycodone shipped in April 2017 (approximately fifteen times the median order for Wilkinson); 12,000 dosage units of hydrocodone shipped in September 2015 (approximately twelve times the median order for Wilkinson); and three orders totaling 36,000 dosage units of hydrocodone shipped in September 2014 (each order approximately twelve times the median order for Wilkinson). ALJ-1, at 14, paras. 93(a)-(c). Morris & Dickson shipped controlled substances to Wilkinson despite being aware of red flags for diversion. Morris & Dickson failed to conduct adequate due diligence sufficient to resolve those red flags and failed to report suspicious orders to DEA. ALJ-1, at 14-15, paras. 91, 96-97.

9. **Hephzibah Pharmacy, L.L.C. ("Hephzibah"):** Morris & Dickson shipped 92 orders of oxycodone (18,620 dosage units) and 57 orders of hydrocodone (21,800 dosage units) to Hephzibah between April 2017 and June 2017. ALJ-1, at 12, para. 71. Morris & Dickson shipped these orders to Hephzibah after having received a report from a third-party vendor that raised red flags concerning Hephzibah's dispensing practices, without conducting adequate due diligence to resolve those concerns. *Id.* at 11-12, paras. 69-70, 72-73, 75. In December 2017, Morris & Dickson reported that it had closed the Hephzibah account due to Morris & Dickson's due diligence efforts, but it had not found

Hephzibah to have exhibited suspicious activity or excessive orders. *Id.* at 12, para. 77. Morris & Dickson shipped all the orders placed by Hephzibah. *Id.* at 12, para. 78.

THE WITNESSES

I. The Government's Witnesses

The Government presented its case through the testimony of six witnesses and the introduction of 70 exhibits. The Government's first witness was **Thomas Prevoznik** ("Prevoznik"), the Acting Section Chief of the Pharmaceutical Investigation Section of the DEA. Tr. 47-87. Prevoznik has been with the DEA for 28 years and began his career as a Diversion Investigator. Tr. 48. Prevoznik provided background information about his training, career progression, and duties within the DEA. Tr. 48-52. Prevoznik discussed the controlled substances that are currently sought for illicit use, such as oxycodone, hydrocodone, benzodiazepines, lorazepam, gabapentin, Neurontin, and Soma, and he described the opioid crisis in the United States. Tr. 52-54. He noted that the regulated community recognizes the term "trinity drug cocktail," which is a combination of an opioid, a benzodiazepine, and a muscle relaxer. Tr. 55. Prevoznik also provided an overview of the Controlled Substances Act ("CSA"), and what distributors are required to do to comply with the CSA. Tr. 57-62, 76-83. Prevoznik provided information concerning outreach programs the DEA conducted for distributors. Tr. 62-69. Prevoznik explained the purpose of the Automation of Records and Consolidated Ordering System ("ARCOS"), and that distributors are required to report their transactions of controlled narcotics in Schedules I-III, and other specified controlled substances. Tr. 69-72. Prevoznik identified Government Exhibits 3, 4, 65, 66, and 69. Tr. 62-65.

Prevoznik presented as a professional, objective regulator who had no stake in the outcome of the case. Further, Prevoznik provided testimony that was sufficiently detailed, plausible, consistent, and cogent to be fully credible, with one exception. That exception concerns his testimony that a distributor is only required to report orders that it suspects might be diverted. Tr. 60, 85-87. Because that testimony is inconsistent with 21 C.F.R. § 1301.74(b), I do not credit it. That section requires reporting of suspicious orders and gives examples, such as orders of unusual size or frequency, or exhibiting an abnormal pattern. The section does not indicate that those examples must also be linked to a suspicion that the orders will be diverted.

Prevoznik's testimony on this matter is also inconsistent with the expert testimony of Joel Dunn. Tr. 497-98.

The Government's second witness was **David Lemoine** ("Lemoine"). Tr. 88-132. Lemoine began his career with the DEA in 2013 as a Diversion Investigator. He now works with the New Orleans Field Division Technical Operations Group. Tr. 89. He provided testimony concerning his training and experience with DEA, prior to his involvement in the current case. Tr. 89-92. Lemoine testified about why the DEA started investigating the Respondent in November 2017, and how that investigation was conducted. Tr. 92-101. During the investigation, the Respondent provided details of its suspicious order monitoring program to DEA. Tr. 93. Lemoine identified Government Exhibits 6, 7, 8, 9, and 10. Tr. 94-101.

Lemoine presented as a professional, objective regulator who had no stake in the outcome of the case. Further, Lemoine provided testimony that was sufficiently detailed, plausible, consistent, and cogent to be fully credible.

Robin Hogue ("Hogue") was the third witness called by the Government. Tr. 142-86. Hogue is a Diversion Investigator for the DEA and she began her employment with the DEA in 2015. Tr. 142-43. Hogue briefly discussed her prior experience and training. Tr. 143. Hogue testified that she became the primary case agent of DEA's investigation of the Respondent in March 2018. Tr. 143-44. The remainder of Hogue's testimony consisted of identifying Government documents. Hogue identified Government Exhibits 11-63, 68, and 71. Tr. 144, 147-177.

Hogue presented as a professional, objective regulator who had no stake in the outcome of the case. Further, Hogue provided testimony that was sufficiently detailed, plausible, consistent, and cogent to be fully credible.

The Government next presented the testimony of **Gamaliel Rose** ("Rose"). Tr. 187-245. Rose attended Yale University and he also received a Master's of Business Administration with a concentration in statistical analysis from the Darden School of Business. Tr. 188. After earning his MBA, Rose worked as an analysis consultant and statistician. Tr. 189. He joined DEA in 1999 as a management analyst. Tr. 189, 218. In 2003, Rose became a program analyst in the office of DEA's Deputy Administrator. Tr. 218-21. He then joined DEA's statistical analysis unit in 2006 and was promoted to section chief of that unit in 2008. Tr. 190, 222. The statistical analysis unit develops "statistical analyses for top management to help allocate resources,

identify targets, problems, and to take any other problems that would come along from" other sections of DEA. Tr. 190. Rose has been the Chief of the Statistical Services Section of the DEA since 2008. Tr. 188. As Section Chief, Rose "supervise[s] the analysis process" and makes sure the DEA has "high-quality data that [it] can rely on for proceedings like this" and to make informed decisions in the execution of DEA's work. Tr. 190.

Rose has developed and implemented statistical models related to the pharmaceutical industry. Tr. 191-92. Rose was qualified, without objection, as an expert in "developing and implementing statistical models and methods of analyzing large and complex data sets." Tr. 192.

For his work on DEA's investigation into Respondent, Rose was asked to apply a statistical model that his section had developed and applied in other investigations. Tr. 193. Initially, Rose was provided a set of ARCOS data concerning Respondent's oxycodone and hydrocodone sales from January 1, 2014 to September 30, 2018. Tr. 193-94, 217. Rose obtained the data from the ARCOS unit. Tr. 193. He later obtained data of Respondent's sales of oxycodone and hydrocodone through April 30, 2019. Tr. 194.

In conducting his analysis, Rose looked at transactions, meaning the number of dosage units of oxycodone and hydrocodone that Respondent sold to various pharmacies. Tr. 196. Rose then compared every transaction of one pharmacy made during a fixed time period against every other transaction of that pharmacy made during the same time period. Tr. 197, 226-27. Rose called this a fixed-frame analysis. Tr. 197. Rose's analysis compared a single transaction against all other transactions made by the same pharmacy during "a fixed frame of four years" from January 1, 2014 to April 30, 2018.[1] Tr. 198. This type of analysis is easier to do than "the more onerous and more complex" moving-frame analysis. Tr. 198, 227. Rose explained that there was no material difference in the outcome between a fixed-frame and a moving-frame analysis. Tr. 198-99, 227-28. Both types of analysis "produce the same basic result, which is to identify a body of outliers that . . . would be worthy of further study." Tr. 199. The results of Rose's analysis are based on the easier fixed-frame method because he was looking for "a ballpark estimate of scale, of size of outlier population," not the exact number of outliers. Tr. 227, 234. He also conducted a moving-frame analysis which produced results "consistent with what [he] found using the" fixed-frame method. Tr. 228, 235. In his moving-frame

[1] At one point during his testimony, Rose stated that his analysis went through the end of the 2018 calendar year. Tr. 198. He later stated that the analysis included transactions through April 30, 2018. Tr. 226.

analysis, Rose looked at "the entire population" and not only the eight exemplar pharmacies in the OSC. Tr. 230.

Rose applied the Tukey method to perform his analysis of Respondent's oxycodone and hydrocodone transactions. Tr. 199. Rose believed the Tukey method was easier to apply to the data than a standard deviation model. Tr. 236. He used the Tukey method because it is "a more flexible method for dealing with" irregular distribution patterns. Tr. 199. Rose got the idea to use the Tukey method from Respondent's expert, Mr. Kenneth A. Weinstein. Tr. 200, 237. The Tukey method is widely-recognized as a reasonable method to identify statistical outliers. Tr. 200, 209, 236-37.

The Tukey method uses the first and third quartiles of a data set to identify outliers. Tr. 201-02. The first quartile is the 25th percentile and the third quartile is the 75th percentile. Tr. 201. The Tukey method uses the first and third quartiles as markers for identifying outliers below the 25th percentile and above the 75th percentile. Tr. 201. The interquartile range ("IQR") is the difference between the first and third quartiles, which is then multiplied by a factor of 1.5 to 6. Tr. 202. The IQR multiplier is applied to the third quartile, or 75th percentile, to identify "approximate indications of . . . unusuality." Tr. 202. The specific IQR multiplier used depends on the level of "rigor or onus you're trying to put on the data." Tr. 202. Applying a lower IQR multiplier, such as 1.5, would produce more outliers than a higher IQR multiplier. Tr. 202-03. DEA did not want to be "overly onerous" on registrants so Rose applied an IQR multiplier of 3 instead of 1.5. Tr. 202-03. Rose used an IQR multiplier of 3 because he found it to "work[] very well at identifying what are called far out or extreme outliers." Tr. 203, 233, 242. By using 3 IQR, Rose calculated a smaller group of outliers than he would have had he used 1.5 IQR. Tr. 203. There are situations where it is appropriate to use an IQR higher than 3. Tr. 202, 234.

Rose testified that his analysis of Respondent's sales from January 1, 2014 to April 30, 2018, identified 7,252 oxycodone sales and "just under 5,000" hydrocodone sales that were outliers. Tr. 212. He also testified about the number of outlier transactions with respect to seven of the exemplar pharmacies in the OSC. Tr. 213-14, 216-17, 243.

Rose also performed a Tukey analysis for the OSC/ISO. Tr. 204. This analysis was incorrect because one of Rose's analysts applied 3 IQR to the median of the data set, or the 50th percentile, instead of the 75th percentile. Tr. 204, 208-09. This incorrect analysis produced "a

much larger group of outliers." Tr. 209. When Rose realized the mistake, he corrected the analysis and had his analyst "go back and check every other analysis he had done, and he verified that they all had been done correct." Tr. 209.

The Government also called Rose as a rebuttal witness to address one of the criticisms leveled by the testimony of the Respondent's expert witness concerning the methodology Rose had used to identify outliers. Tr. 1083-93. Rose also did an analysis of the Respondent's orders using the look-back analysis, which the Respondent's expert suggested was a better approach. Tr. 1083. Using the look-back analysis Rose examined every transaction against the other transactions of the same pharmacy and compared it against the pharmacy's orders in the previous 365 days. Tr. 1084-85. Rather than the fixed-frame analysis that Rose had originally performed, the new analysis used a moving, dynamic frame. Tr. 1083. The analytical frame moved every day. Tr. 1085. In conducting this second analysis, Rose used an IQR multiplier of 3. Tr. 1085. Government Exhibits 73 and 74 contain the results of Rose's look-back analysis. Tr. 1089. Using the look-back analysis Rose identified 6,816 outliers for oxycodone, rather than 7,252 that he had identified using the fixed-frame analysis. Tr. 1091. This was a reduction of 6 percent. Tr. 1091. Using the look-back analysis Rose identified 5,222 outliers of hydrocodone, rather than 4,948 that he had identified using the fixed-frame analysis. Tr. 1092. This was an increase of 5.5 percent. Tr. 1091. In Rose's opinion, the results of the fixed-frame analysis and the look-back analysis for oxycodone and hydrocodone were substantially similar. Tr. 1091-92.

Rose presented as a professional, objective regulator who had no stake in the outcome of the case. Further, Rose provided testimony that was sufficiently detailed, plausible, consistent, and cogent to be fully credible.

The Government's final witness was **Joel Dunn** ("Dunn"). Tr. 277-498. Dunn has worked for DEA since 2004. Tr. 278. Dunn spent his first ten years with DEA as a diversion investigator in Dallas, Texas, where he was assigned to the tactical diversion squad and became a senior diversion investigator. Tr. 278-79. He attended a 13-week training course in Quantico to become a diversion investigator. Tr. 278. He then spent three years as the staff coordinator of DEA's special operations division ("SOD"). Tr. 279. At SOD, Dunn investigated matters involving international diversion. Tr. 281. He is currently Group Supervisor of DEA's New Orleans Field Division. Tr. 278. Dunn holds a bachelor's degree from the University of Texas at Arlington and a law degree from Wesleyan University. Tr. 279, 485.

When Dunn was a senior DI in Dallas, he taught half-day training sessions on pharmaceutical diversion at the basic narcotic investigator school hosted by DEA. Tr. 280. He also conducted "quite a bit of training" when he worked in the special operations division, including three trips to Canada where he taught the Royal Canadian Mounted Police about controlled substance diversion in the United States. Tr. 280.

As group supervisor of the New Orleans Field Division, Dunn oversees the work of diversion investigators, registration technicians, and a group assistant. Tr. 279. He provides "subject matter expertise" to the diversion investigators on their investigations. Tr. 279-80. Dunn has worked on diversion investigations for the last 14-15 years. Tr. 280. He also teaches a for-credit course about pharmaceutical regulation at Tulane University Medical School. Tr. 281. He has also taught at Xavier University School of Pharmacy concerning regulations pertaining to pharmacists and red flags that a pharmacist should be aware of. Tr. 281, 486. In addition to teaching at schools, Dunn has also provided training to federal prosecutors on diversion, including a recent training for Assistant United States Attorneys. Tr. 281-82. The training Dunn has offered to schools and prosecutors includes how to identify red flags. Tr. 485-86.

Dunn was accepted, without objection, as "an expert in the identification of common red flags suggestive of an illicit pharmaceutical operation and as well as with respect to the requirements imposed on DEA registrants to identify and investigate such red flags when they become aware of them." Tr. 282.

Dunn testified that 21 C.F.R. § 1301.74(b) requires distributors "to devise and maintain a system to detect suspicious orders." Tr. 283. The same regulation provides that "orders of unusual size, [unusual] frequency, or deviating from a standard pattern" are characteristics of a suspicious order. Tr. 283. This list is not exhaustive. Tr. 283. DEA regulations also require distributors to report suspicious orders to DEA upon discovery of the suspicious order. Tr. 283. Dunn testified that DEA's reporting requirement is important for three reasons. Tr. 283-84. First, if the distributor fails to report a suspicious order, DEA has "no way of knowing it occurred" and cannot investigate that order. Tr. 283-84. Second, orders of Schedule II and III drugs are reported to DEA on a quarterly basis, so a distributor will be able to report a suspicious order to DEA much faster than waiting for the ARCOS report. Tr. 284. Third, ARCOS does not include data of orders for all controlled substances. Tr. 284.

Dunn also explained why DEA is concerned about large shipments of controlled substances to retail pharmacies. Tr. 285. First, he explained that an order of unusual size would be an order "outside of the typical market for that particular pharmacy." Tr. 285. Second, he testified that large orders of controlled substances present a greater risk of diversion. Tr. 285-86. Schedule II narcotics, such as oxycodone and hydrocodone, and Schedule II amphetamines are of specific concern to DEA because "they are the most abused controlled substances" and "have the highest street values." Tr. 286. Dunn also testified that it is more concerning to DEA when large shipments of controlled substances go to small, independent pharmacies rather than when they go to chain pharmacies with national reach. Tr. 286-87.

There are different ways for DEA to determine whether an order of controlled substances is unusually large. Tr. 292. For example, DEA can conduct a statistical analysis or compare a pharmacy's orders of controlled substances against past orders to see if its orders have increased significantly. Tr. 292.

Dunn supervised the DIs on their investigation of the Respondent. Tr. 291-92. As part of the investigation, Dunn requested Rose's group to conduct a statistical analysis of the Respondent's orders of controlled substances to see how many orders were of an unusual size. Tr. 293, 403-04. Dunn asked Rose to conduct an analysis "to get a sense of just mathematically quantifying how many suspicious orders could theoretically have been missed by Morris & Dickson." Tr. 404. The results of Rose's analysis of Respondent's orders revealed about 14,000 orders that should have been reported as suspicious. Tr. 294. Dunn's investigation found three suspicious order reports filed by the Respondent. Tr. 294. The Respondent shipped the orders related to the three suspicious order reports that it filed. Tr. 294. A distributor should not ship an order once it identifies that order as suspicious. Tr. 294.

DEA requires a distributor to conduct due diligence when a distributor identifies a red flag. Tr. 295, 298, 301-02. The distributor must exercise due diligence in investigating the red flags it identifies and resolving those red flags before it ships the controlled substances. Tr. 295, 298, 301-02. It would not be proper to ship controlled substances before resolving red flags. Tr. 302. For example, if a distributor identifies that a pharmacy it sells to is dispensing an unusually high volume of oxycodone, the distributor should conduct due diligence to ensure those prescriptions are "going to a legitimate medical purpose." Tr. 298. During DEA's investigation, Dunn requested the Respondent's due diligence files. Tr. 295. A distributor must

document the due diligence it conducts. Tr. 298, 302. It would be difficult for a distributor to prove that it conducted due diligence if it failed to document the steps it took. Tr. 298-99, 302-03.

There are similarities and differences between red flags for distributors and red flags for practitioners. Tr. 297. Red flags for distributors include a pharmacy that: dispenses a high volume of narcotics; dispenses the trinity drug cocktail; fills prescriptions for customers who live far away from the pharmacy; fills prescriptions for a high volume of patients who pay for prescriptions in cash. Tr. 297, 300-01. It is a red flag for a pharmacy to order and dispense disproportionally more controlled substances than non-controlled substances. Tr. 299. It is also a red flag if a pharmacy orders "excessive quantities of a limited variety of controlled substances." Tr. 300. Dunn testified that DEA views one trinity prescription as a high volume. Tr. 300, 353.

The Respondent's Standard Operating Procedures ("SOP") Manual says that the Respondent "keeps a system in operation which is designed to discover those purchasing patterns of controlled substances which exceed the norm and could possibly be related to diversion activities." Tr. 307; GE-18, at 19. Dunn testified that the requirements of 21 C.F.R. § 1301.74(b) are "a little more encompassing than just the statement exceed the norm." Tr. 307. Based on the Respondent's SOP Manual, Dunn testified that the Respondent's suspicious order monitoring program did not look for the things required under 21 C.F.R. § 1301.74(b). Tr. 307-08.

The Respondent's SOP Manual describes three methods for identifying suspicious orders: Controlled Drug Volume Analysis Program; Management Oversight; and Employee Oversight. GE-18, at 19-20.

Dunn testified that DEA received documents in response to several subpoenas DEA served on the Respondent. Tr. 389. The Respondent's SOP Manual describes a Controlled Drug Volume Analysis Program that generates a monthly report that is reviewed by management. Tr. 308; GE-18, at 19. Dunn does not recall seeing one of these reports in any of the documents the Respondent produced in response to DEA's subpoena. Tr. 308. Dunn also does not recall seeing any such report or any reference to such a report in the materials he reviewed concerning the Respondent. Tr. 308-09.

The Respondent's SOP manual states that "[w]hen a suspicious pattern or purchase is identified by any of the above methods the customer is contacted in some but not all cases and asked for a written explanation for the unusual order. In all cases, a letter is sent to the DEA indicating a possible suspicious order." GE-18, at 20; Tr. 311-12, 391. In Dunn's opinion, this does not comply with DEA's regulations. Tr. 312.

The bulk of Dunn's testimony on direct examination was devoted to the Pro-Compliance Reports and Market Basket Analyses for the pharmacies listed in the OSC. Tr. 329-85, 402-03. Dunn did not review all of the Pro-Compliance Reports he received. Tr. 403. Dunn did not know how many Pro-Compliance Reports were received by DEA, but when Respondent's counsel asked, "If I represented to you that it was 7,999, would that sound in the ballpark?", Dunn answered, "It very well could." Tr. 403. Dunn also could not recall how many Market Basket Reports were received by DEA, but testified that he had no reason to disagree with Respondent's counsel's representation that it was about 42,000. Tr. 407. At the top of each Market Basket Report, there are two boxes labelled volume of controlled substances and total volume. GE-58, at 1; Tr. 408-09. Dunn believed the numbers in these boxes referred to dosage units and he does not know whether they in fact referred to dollar amounts. Tr. 408-09. He never asked whether the numbers represented dosage units or dollars. Tr. 409. Dunn testified that he believes analyzing a pharmacy's total cash volume is an arbitrary standard because it would include payments for non-controlled drugs and some non-controlled drugs are "extremely expensive" while controlled substances are "relatively cheap." Tr. 425.

Dunn testified about how a distributor may go about conducting due diligence of its customers. Tr. 392-95. Dunn never personally asked anyone who worked for the Respondent about the Respondent's policies. Tr. 397, 399-400. Dunn's testimony about the Respondent's policies is based on his own interpretation of the documents. Tr. 400.

Even though the Respondent produced some due diligence files to DEA, Dunn testified that a distributor "can conduct due diligence and ignore the red flags that are in [its] face and continue to ship. And that's what I feel like happened in this particular case." Tr. 463.

Dunn presented as a professional, objective regulator who had no stake in the outcome of the case. Further, Dunn provided testimony that was sufficiently detailed, plausible, consistent, and cogent to be fully credible.

The last witness the Government presented was Diversion Investigator **Theresa Bass** ("Bass"). Tr. 1105-11. Bass was called as a rebuttal witness. She briefly testified concerning her work history with the DEA, Tr. 1105-06, and provided testimony about attending a meeting at the Respondent's facility in August 2016, which one of the Respondent's witnesses, Louis Milione, also attended. Tr. 1106-08. Apparently, Bass was called to rebut Milione's testimony about whether the Respondent had attempted to sell a software product to the DEA during the August 2016 meeting. Bass testified that the Respondent was promoting a software program, similar to a prescription monitoring program. Tr. 1107-09.

While Bass presented as a professional, objective regulator who had no stake in the outcome of the case, I do not credit her testimony. Rather, I find the testimony of Milione more credible concerning the rather irrelevant issue raised by the Government of whether the Respondent attempted to sell a product to the DEA at the August 2016 meeting. I find his testimony on this point more credible based on my observation of his testimony and his demeanor as a witness. I also find his testimony more consistent with the content of Respondent Exhibit 11, the Power Point presentation delivered by the Respondent at the August 2016 meeting. A review of that document does not reveal any information concerning a prescription monitoring program. Furthermore, even if I were to credit Bass' testimony, it would have absolutely no effect on my assessment of Milione's credibility. In short, there was no need to call Bass as a witness.

II. The Respondent's Witnesses

The Respondent presented its case through the testimony of three witnesses and the introduction of 10 exhibits. The Respondent's first witness was **Kenneth A. Weinstein** ("Weinstein"). Tr. 501-689. Weinstein has been the Vice President of the consulting firm Analysis Group, Inc. ("AGI") for the past two-and-a-half years. Tr. 501-02. As Vice President of AGI, Weinstein leads consulting teams on projects related to the healthcare and pharmaceutical industries. Tr. 502. He has advised clients on matters involving controlled substances, the False Claims Act, kickbacks, and issues related to healthcare litigation. Tr. 502.

Weinstein received an undergraduate degree in 2003 from Harvard University in applied mathematics and economics. Tr. 504. In 2008 Weinstein earned a Master's in Business

Administration from the Massachusetts Institute of Technology ("MIT"). Tr. 504. Between Harvard and MIT Weinstein worked on litigation-related issues as an analyst and then senior analyst at AGI. Tr. 504-05. After earning his Master's Degree, Weinstein spent two years at Bridgespan Group, a consulting firm that serves government and non-profit agencies. Tr. 505. In 2010 Weinstein became an associate at AGI and was promoted to a manager in 2012. Tr. 505-06. He became Vice President in 2017. Tr. 506. Weinstein authenticated Respondent Exhibit 14, pages 15 to 19, and Exhibits 28 and 29. Tr. 506, 562-68.

Since re-joining AGI in 2010, Weinstein has worked on matters involving pharmaceutical manufacturers, distributors, pharmacies, and clinics. Tr. 508. He has had about 15 clients in these areas of the pharmaceutical industry since 2010. Tr. 508-09. He has worked specifically with manufacturers and distributors of controlled substances. Tr. 509. He has assisted several distributors and manufacturers in developing suspicious order monitoring ("SOM") systems. Tr. 509-10, 514. He has also developed SOM programs for a pharmacy chain. Tr. 514. He has also worked on projects involving the analysis of dispensing data to identify red flags and "to assist compliance with effective controls against diversion." Tr. 510. Weinstein agreed that cash payments and distance travelled by the patient can be red flags of diversion. Tr. 648-49. Weinstein added that these red flags cannot be identified by a distributor at the time an order is placed. Tr. 648-49. Further, Weinstein testified: "I'm not sure that I've seen guidance on red flags of dispensing diversion that state that a distributor cannot make subsequent shipments of controlled substances." Tr. 649.

Weinstein has made presentations to DEA and the Department of Justice regarding AGI's application of statistical modeling to controlled substances, specifically the application of the Tukey method. Tr. 510-11, 513. He has also presented on controlled substances to the Illinois Department of Public Health. Tr. 511. He has co-published articles on Law360 about the challenges of identifying suspicious orders, such as limited data and identifying orders in real time, and on opioid guidelines issued by the Center for Disease Control. Tr. 512, 520. In one of those articles, Weinstein opined that under the DEA's Final Order in *Masters Pharmaceuticals, Inc.*,[2] DEA views potentially suspicious orders as guilty until proven innocent. Tr. 651. In the same article he wrote that the *Masters* Final Order establishes a high bar for dispelling suspicion. Tr. 651.

[2] 80 Fed. Reg. 55418 (2015), *pet. for rev. denied*, 861 F.3d 206 (D.C. Cir. 2017).

Weinstein has applied the Tukey analytical model in developing SOM programs and in identifying outliers. Tr. 512-13, 521. Tukey is not the only method used in SOM programs, but it is a common one. Tr. 521-22. Weinstein agrees, however, that statistical analysis is an appropriate method for identifying suspicious orders. Tr. 654. He also agrees that the Tukey method is an appropriate method to conduct that analysis. Tr. 654.

In his work with pharmacies, Weinstein has interviewed pharmacists, warehouse staff, and compliance officers to gain an understanding of the business context and of "what would be helpful to them in reviewing red flags." Tr. 515-16, 519. By working with pharmacies Weinstein gained experience of how pharmacies manage their inventories and order new stock. Tr. 517-18. He has also looked at how pharmacists exercise their corresponding responsibility when dispensing controlled substances. Tr. 519. In his work with distributors, Weinstein has interviewed compliance officers and logistics staff. Tr. 515-16. Through this work, he has gained an understanding of how a distributor receives orders from pharmacies. Tr. 516. Weinstein has also gained experience of how controlled substances are regulated. Tr. 518.

Weinstein has attended several conferences related to the pharmaceutical industry, including the Healthcare Distribution Association; a controlled substances summit hosted by the American Conference Institute; the American Society for Pharmacy Law Conference; a pharmacy law symposium organized by the law firm Quarles & Brady; and the Prescription Drug Abuse Summit in Atlanta, Georgia. Tr. 520.

Weinstein was accepted as an expert, without objection, in statistical analysis related to controlled substance distribution and as an expert in pharmacy ordering and inventory management. Tr. 513-14, 520-21.

Weinstein highlighted two advantages to using the Tukey method to identify outlier transactions. Tr. 522. First, the Tukey method omits "anything that's extreme at the top or the bottom." *Id.* Second, the Tukey method works well with non-standard distribution patterns. *Id.*

The Respondent's law firm hired AGI to review the DEA's statistical analysis of suspicious orders in the OSC/ISO and to enhance the Respondent's "statistical approach" to monitoring orders of controlled substances. Tr. 502-03, 560, 644. Weinstein and AGI began working on the Respondent's SOM system in May 2018 shortly after DEA issued the OSC/ISO against Respondent. Tr. 560, 577, 640. Weinstein testified that AGI is being paid by the hour and payment is not contingent on its findings. Tr. 503.

Weinstein was also retained to analyze Rose's work in this case. Tr. 524. Weinstein testified that he "was able to confirm that [Rose's] math follows his description of the analysis." Tr. 557-58. Weinstein, however, was of the view that Rose's fixed-frame analysis produced unreliable results. Tr. 528. Weinstein also opined, however, that Rose's findings, contained on page 11 of the Government's demonstrative exhibits[3], do not accurately reflect the number of orders that the Respondent should have reported to DEA. Tr. 525, 558. In general, the main flaw of Rose's analysis, in Weinstein's opinion, is Rose's failure to consider context. Tr. 526, 541-42. More specifically, Weinstein opined that the deficiencies in Rose's analysis can be attributed to Rose's (1) use of a four-year fixed-frame as opposed to the look-back method; (2) his failure to consider the schedule change of hydrocodone; (3) failure to consider package size and formulation; and (4) use of the line item approach as opposed to a cumulative approach. Tr. 558. Weinstein testified about the contextual considerations that, in his opinion, paint a more accurate picture of which orders were outliers. Tr. 541-42. In Weinstein's opinion, statistical analysis alone is insufficient to identify diversion of controlled substances because there are contextual elements that cannot be gleaned from a pharmacy's ordering data. Tr. 558-59.

With respect to the first deficiency, Weinstein explained that Rose "us[ed] data that wasn't available at the time for any given order." Tr. 525. Weinstein testified that Rose's fixed-frame analysis took into account the entire time period of January 1, 2014 to April 30, 2018, to determine the outlier threshold and then compared all the orders against that threshold. Tr. 526-27. Weinstein understood Rose to testify that the Respondent could not have performed this analysis at the time it received an order in 2014, for example, because data from 2015-18 would not have been available at that time. Tr. 527. Weinstein testified that Rose's fixed-frame analysis is something a distributor could not do. Tr. 527. A distributor is obligated to evaluate an order for suspicious characteristics at the time the order is placed and the distributor cannot compare that order to transactions that have not yet occurred. Tr. 527-28. Weinstein opined that Rose's use of a fixed-frame analysis and failure to consider context renders his results unreliable. Tr. 528, 541. Weinstein also testified, however, that a fixed-frame analysis "wouldn't have an

[3] The Government's Demonstrative Exhibits are contained in ALJ-63, and will be cited to hereinafter as GDE. The Respondent's Demonstrative Exhibits, hereinafter RDE, are not contained in an ALJ exhibit, but they will be certified as part of the record and transmitted to the Acting Administrator in accordance with 21 C.F.R. § 1316.65(c).

impact on the results" was it not for some changes in the industry during the relevant time period. Tr. 528.

For Weinstein's review of Rose's analysis, he compared orders against transactions from the previous 12 months. Tr. 528-29, 659-60. Under this "look-back" approach where Weinstein looked back "only to the prior year, rather than to the full four years," Weinstein did not identify many of the orders identified in Rose's analysis. Tr. 528-29. Weinstein's analysis showed that over 60% of the orders from the seven exemplar pharmacies[4] in 2017 and 2018 identified as outliers by Rose "would not have been identified if compared only to the prior year." Tr. 529-31, 539. Further, about 50% of the orders from all customers identified by Rose as outliers in 2017-18 would not have been considered outliers if those orders were compared only to the prior year. Tr. 529-30, 568. Weinstein then testified about the results of comparing his analysis to Rose's analysis as represented on Respondent Demonstrative Exhibit 4. Tr. 537-38.

As for the second and third deficiencies, Weinstein testified that Rose did not consider the effects of hydrocodone's schedule change and the drugs' "item and package sizes." Tr. 526, 542. In late 2014 DEA rescheduled hydrocodone from Schedule III to Schedule II. Tr. 539. Because Schedule II is more restrictive than Schedule III, there were fewer orders for hydrocodone after it was rescheduled. Tr. 539. The fixed-frame method compared orders for hydrocodone in 2014 when it was a Schedule III drug to orders in 2015-18 when it was a Schedule II drug. Tr. 539-40. This means orders placed when hydrocodone was a Schedule III drug were identified as outliers based on a comparison to orders placed when hydrocodone was a Schedule II drug. Tr. 539-40. Weinstein also added that Rose's analysis did not take into account package size or formulation, such as pills or liquid form of the drug. Tr. 553, 557. In Weinstein's opinion, this consideration makes a difference. Tr. 553-54.

With respect to the fourth deficiency, Weinstein explained that he considered in his analysis whether a pharmacy placed all of its orders for a particular substance as one line item or as multiple line items. Tr. 543-44, 551-52. For example, looking at Respondent Demonstrative Exhibit 6, DEA identified an order of 2,000 dosage units of oxycodone placed by Bordelon's on March 12, 2018, as unusually large. Tr. 544-45. Weinstein noted, however, eight other orders of 2,000 dosage units of oxycodone placed by Bordelon's that DEA did not identify as unusually large. Tr. 544-45. The difference, Weinstein explained, is due to the fact that the March 12,

[4] Wallace, Bordelon's, Folse, Pharmacy Specialties, Dave's, Wellness, and Wilkinson. GDE, at 11.

2018 order was placed as a single line item for 2,000 dosage units while the other eight orders were for 2,000 dosage units broken across multiple line items. Tr. 544-45. For example, on March 22, 2017, Bordelon's ordered 2,000 dosage units of oxycodone broken down into two line items of 100 units, one line item of 300 units, one line item of 500 units, and one line item of 1,000 units. Tr. 545, 547-48.

In Weinstein's opinion, 2,000 dosage units of oxycodone was not an unusually large amount of oxycodone for Bordelon's to order, but it appeared unusually large compared to other orders for oxycodone that contained multiple line items of smaller amounts of the drug. Tr. 545-46. Weinstein opined that the order placed by Bordelon's on March 12, 2018, for 2,000 dosage units of oxycodone was not an outlier. Tr. 552. The only difference, in Weinstein's view, is how the order was entered into the system. Tr. 546. Because of this, Weinstein believes a distributor should look at the cumulative amount of a substance that is ordered and not individual line items. Tr. 546-47. Weinstein, however, did not incorporate this cumulative-based approach in any analysis he did in this case, including the analysis he conducted to produce the results reflected in Respondent Demonstrative Exhibit 4. Tr. 551.

Weinstein believes it is not possible to correct Rose's analysis for the problems caused by using a line item approach. Tr. 550, 552. In Weinstein's view, Rose's line item approach produced outliers that would not have been identified under the cumulative approach. Tr. 552. Weinstein also testified that Rose's line item approach misses outliers. Tr. 552-53. Ten thousand dosage units would be an "enormous" volume of controlled substances, but it would not be flagged by a line item approach if the 10,000 dosage units were ordered as 100 separate line items of 100 dosage units. Tr. 552-53.

An effective system for identifying suspicious orders, in Weinstein's opinion, should take a cumulative approach and consider factors such as package size, formulation, and brand name or generic versions of the drug. Tr. 554-57. A system that fails to take these types of factors into account may result in the distributor over-reporting orders that are not unusual and not suspicious. Tr. 556.

AGI began its work by developing "interim thresholds based on an enhanced statistical approach to evaluating Morris & Dickson's orders." Tr. 561. This involved establishing and implementing "item group thresholds for each customer by month." Tr. 561. Weinstein applied these interim thresholds to retail pharmacies and alternate care customers. Tr. 569. Weinstein

described an alternate care customer as a pharmacy that exclusively serves a particular facility or patient population and is not open to the general public to fill prescriptions on a walk-in basis. Tr. 570. The Respondent implemented the interim thresholds in May-June 2018 and kept them in place until October 2018 for retail pharmacies and January 2019 for alternate care customers. Tr. 570-71, 577, 667. The Respondent began operating an interim, automated SOM program within a few weeks of retaining AGI. Tr. 577-78. The Respondent implemented a permanent system for retail pharmacies on October 1, 2018, and a permanent system for alternate care customers on January 1, 2019. Tr. 579-80. Weinstein testified that comparing data from a retail pharmacy against an alternate care pharmacy is like comparing apples to oranges because they operate under different business models. Tr. 580, 639. In Weinstein's view, it is important to compare a pharmacy's orders to other pharmacies within the same peer group. Tr. 580-81.

Weinstein and AGI looked at DEA regulations on suspicious order monitoring, specifically 21 C.F.R. § 1301.74(b), and DEA guidance letters in designing the system for the Respondent. Tr. 626, 630, 634. Weinstein explained how the system looks for unusual size, deviations from a normal pattern, and unusual frequency. Tr. 627-29.

The Respondent's SOM program that Weinstein and AGI developed performs three core assessments: a monthly assessment based on the customer's ordering history; a monthly assessment comparing the customer to its peer group; and a daily assessment of "the highest priority item groups." Tr. 619. Respondent Demonstrative Exhibit 8 depicts how the peer group, own history, and daily assessments work in the Respondent's SOM system. Tr. 632-37. Other components of the system include peer and item group definitions. Tr. 619. The item groups are classified "into different levels of diversion risk that help determine exactly what statistical parameters are applied to each" item group. Tr. 572-76, 619. The item groups are divided into four categories of risk: priority (highest risk); high-risk subset consisting of oxycodone 30 mg; high risk; and other. Tr. 620-21. These risk classifications and their corresponding Tukey multipliers are depicted on Respondent Demonstrative Exhibit 9. Tr. 621-22, 655-56. When the SOM system identifies an outlier, the order is held for further review. Tr. 582, 625, 629. AGI has recommended to the Respondent the types of information it should look at when reviewing an outlier. Tr. 582. The Respondent looks at Enhanced Customer Profile data when an order is flagged. Tr. 641-42.

Weinstein testified that he continues to interact with the Respondent's staff, and members of the Respondent have provided feedback on how the system can be enhanced. Tr. 640, 643. In Weinstein's expert opinion, the Respondent is capable of identifying suspicious orders without outside assistance. Tr. 643.

Weinstein apparently was called as a witness for two reasons. First, Weinstein's testimony was presented to discredit the reliability of Rose's analysis concerning the number of outlier orders the Respondent had received between January 2014 and April 2018. Second, Weinstein's testimony was presented to demonstrate the effectiveness of the remedial measures the Respondent has taken to ensure that it is in compliance with laws and regulations concerning controlled substances.

With respect to the first reason, I do not find that Weinstein's testimony, or the Respondent's other evidence, discredits the reliability of Rose's analysis. I make this finding for several reasons. First, both experts agreed that the Tukey method is an appropriate method of statistical analysis to identify outlier transactions. Second, while Weinstein testified about four deficiencies in Rose's analysis, a close evaluation of those alleged deficiencies does not support Weinstein's premise. For example, Weinstein faulted Rose's analysis because Rose used a fixed-frame analysis rather than the look-back analysis Weinstein believes is superior, and Rose did not consider context. Yet Weinstein did not back up that assertion with convincing objective data, and he did not apply his look-back analysis to all of the available ARCOS date. When Rose accepted that challenge and used the look-back method to examine all of the relevant ARCOS data, the unrebutted results were substantially similar. Tr. 1091-92; GE-73-74. Those results significantly undercut all four of the deficiencies asserted by Weinstein. Third, the Respondent's own evidence undercuts Weinstein's assertions. In an effort to demonstrate its current and future compliance with DEA regulations, the Respondent introduced 58 suspicious order reports that it filed with the DEA in a period of less than three months. RE-20. In those 58 reports, the Respondent informed the DEA of about 3,915 suspicious orders. Thus, using a system designed by Weinstein, the Respondent identified close to 4,000 orders in less than 3 months, whereas Rose identified approximately 12,200 outlier orders that occurred over a period of 4 1/3 years. Granted, the Respondent only presented its suspicious order reports for the period from May 14, 2018 through July 29, 2018, but Weinstein testified that he had run the Respondent's sales data from a few months in early 2018, and he identified suspicious orders "in

a similar number to what's being identified currently." Tr. 666. Quite frankly, Weinstein's testimony did not refute Rose's analysis because the objective data is far more convincing than Weinstein's subjective expert testimony.

With respect to the second reason Weinstein was called as a witness, to demonstrate current and intended future compliance with DEA regulations, in part by using Weinstein's algorithms to identify suspicious orders, I find no reason to question his credibility. Certainly, Respondent Exhibit 20 serves as objective evidence of the effectiveness of those algorithms. I do note, however, an inconsistency in his testimony. While he testified that a distributor should evaluate each individual order at the time it is placed, Tr. 546, he also testified that in designing SOM systems, distributors should cumulate orders over time, such as a month's worth of orders. Tr. 555, 557.

Weinstein also testified that statistical analysis alone is not enough to *identify diversion*. Tr. 558-59. This misses the point of the statistical analysis, which was to identify suspicious orders for controlled substances based upon an order being significantly larger than normal. Distributers are to report "orders of unusual size," and that requirement is not linked to answering the question of whether the orders are being diverted for illegitimate purposes. The requirement is to report orders of unusual size, not orders of unusual size that the distributor identifies as being diverted. *See Masters Pharm., Inc.*, 80 Fed. Reg. at 55420, 55478. In addition, Weinstein's testimony that he had not seen guidance on red flags of dispensing diversion that state that a distributor cannot make subsequent shipments of controlled substances without resolving red flags of diversion, Tr. 649, suggests he either has not read, or does not understand, the *Masters* decision. Nevertheless, with the above caveats in the two preceding paragraphs, I find that Weinstein's testimony was sufficiently objective, plausible, and internally consistent. Therefore, I merit it as generally credible in this Recommended Decision, but give greater weight to the testimony of Mr. Rose.

The Respondent next presented the testimony of **Scott Irelan** ("Irelan"). Tr. 693-840. Irelan testified that the Respondent is a privately-held pharmaceutical distributor owned by the Dickson family and that the company has been in operation since 1841. Tr. 694-95. Irelan has worked for the Respondent for 31 years. Tr. 694. Irelan began his employment for the Respondent in 1988 working in the warehouse. Tr. 697. He then became a production manager and managed the Respondent's daily operations of shipping orders to customers. Tr. 697-98,

793. He became the senior operations manager at the end of 2017. Tr. 698, 793. As senior operations manager, Irelan had no involvement in ensuring compliance with DEA regulations. Tr. 698-99.

In May 2018, Irelan unofficially became the Respondent's Director of Corporate Compliance and Security ("Director"). Tr. 699, 791. It was unofficial because the Respondent did not have a corporate title for Director until officially creating that title in June or July 2018. Tr. 699, 791. Irelan's objective as Director is to ensure the Respondent has effective controls in place to prevent diversion. Tr. 700.

Irelan was not involved in the Respondent's due diligence before May 2018, but he "understood basic concepts of due diligence" to the extent it involved delivery drivers observing suspicious activity at stores. Tr. 710, 793. Irelan had no idea what a red flag was before May 2018. Tr. 793. Irelan also had no involvement in or responsibility for the Respondent's SOM system or for reporting suspicious orders from January 2014 to May 2018. Tr. 723, 731-32. He has an understanding, however, of how the Respondent handled suspicious orders based on his review of documents as Director, and his preparation for the hearing. Tr. 732.

As Director, Irelan learned about the Respondent's pre-May 2018 due diligence and compliance efforts by reviewing materials describing the Respondent's SOM system that was in place from January 2014 to May 2018. Tr. 727-28. Irelan also reviewed the company's pre-May 2018 software system when he assumed the role of Director. Tr. 710. The types of due diligence documents that Irelan reviewed are Pro-Compliance Reports, Market Basket Analyses, and information obtained by the Respondent's sales people and delivery drivers. Tr. 712, 719, 730. Irelan also testified later that the Respondent used the same information sources—Pro-Compliance Reports, Market Basket Analyses, and its employees—as the means of identifying suspicious orders. Tr. 730. Irelan testified that he was told by Pro-Compliance that information on Pro-Compliance Reports about the invalidity of a prescriber's DEA registration is not reliable. Tr. 766, 796-98.

Based on the documents he reviewed and the experience he has gained as Director, Irelan believes the Respondent's due diligence practices before May 2018 were insufficient, primarily because the due diligence documentation was "not properly maintained to be . . . easily retrievable." Tr. 720. Irelan also testified that although the Respondent conducted due diligence, that information was not applied at the order level. Tr. 720-21.

Irelan testified that before May 2018 the Respondent conducted "a tremendous amount of due diligence" of its customers. Tr. 704-05. The Respondent, however, did not keep the due diligence documentation "in such a way as to make it . . . easily accessible." Tr. 705, 720. There were due diligence notes on paper, in a database, and in the enhanced customer profile ("ECP"). Tr. 710, 741. Information from the Market Basket Analyses was stored in the ECP. Tr. 715. Irelan acknowledged that prior to becoming the Director he was not in a position to be involved with the Respondent's due diligence efforts, and that his testimony about those efforts before he became the Director was based upon his review of the Respondent's records. Tr. 710.

Irelan testified that he accepts responsibility on the Respondent's behalf for preventing reoccurrence of the Respondent's past failures regarding due diligence; for preventing reoccurrence of the failures of Respondent's old SOM system; and that he accepts responsibility on the Respondent's behalf for correcting the Respondent's failure to report suspicious orders and for preventing the reoccurrence of the Respondent's failure to report suspicious orders. Tr. 721-22, 731-32.

Irelan also testified that he accepts responsibility on the Respondent's behalf for the company's failure to apply its due diligence to orders of controlled substances; for the Respondent's failure to report suspicious orders; for shipping orders without resolving red flags; for the Respondent's SOM system being inconsistent with best practices; and for the Respondent having an insufficient compliance system from January 2014 to May 2018. Tr. 722-23, 730-33, 806-07.

On cross-examination, Irelan testified about specific paragraphs in the Order to Show Cause, and explained why Respondent could or could not accept responsibility for them. Tr. 813, 816-18, 824-25, 827-28, 830-31. Irelan stated he was not in a position to say whether Respondent accepted responsibility for allegations in some paragraphs. Tr. 821-23, 829-30, 832-33.

Irelan testified about the Respondent's old SOM system that was in place from January 2014 to May 2018. Tr. 728-30, 737-38, 740-46, 778. In Irelan's view, the Respondent's pre-May 2018 version of ECP was not as robust as it is currently. Tr. 737-38, 740. Irelan also testified why, in his opinion, the Respondent's old SOM system was inconsistent with best practices. Tr. 729-30, 778.

Irelan then testified about the Respondent's current SOM and ECP systems. Irelan testified about the Respondent's efforts to correct its past failures. Tr. 733. These efforts included recruiting a team of experts and implementing the thresholds developed by Weinstein. Tr. 733-34. The Respondent currently documents its due diligence of suspicious orders in the ECP. Tr. 737. Irelan described ECP as a "one-stop electronic dashboard for all customer due diligence" that presents information in an "instantly retrievable" format. Tr. 737. In his testimony, referring to screenshots in Respondent Exhibit 23A, Irelan offered detailed descriptions of how the current ECP system works, including commentary on how it improved upon the old system. Tr. 747-68. Irelan's testimony highlighted that one of the advantages of the Respondent's current ECP system is that it allows the Respondent to keep all of its due diligence information in an easily accessible format. Tr. 765. Irelan also testified about the process that occurs after the ECP system flags an order as suspicious. Tr. 770-71, 774, 776, 778. He added that the Respondent's current policy is to cancel most suspicious orders. Tr. 770-71, 776. As for reporting suspicious orders, Irelan testified that the Respondent sends a daily email to Group Supervisor Dunn at DEA with an attached Excel spreadsheet that lists all the flagged orders from the previous day. Tr. 779-83.

Irelan presented his testimony in a professional, candid, and straightforward manner. Several aspects of his testimony, however, are cause for concern. I give no weight to Irelan's opinion that the Respondent had conducted a "tremendous" amount of due diligence prior to May 2018. Tr. 704-05, 710. I give it no weight because his testimony is based upon his review of the Respondent's records. Tr. 710. In answering the question of whether those records support a finding that the Respondent had conducted a tremendous amount of due diligence, the records speak for themselves. Irelan's opinion of what the documents say is not relevant.

Second, Irelan was not in a position to be involved with the Respondent's due diligence efforts prior to becoming Director, and virtually all of his testimony about those efforts was based upon a review of the Respondent's records. Tr. 710. Much of Irelan's testimony about those efforts is simply his opinion about what those records demonstrate. I give limited weight to such opinion testimony. *See Wheatland Pharmacy*, 78 Fed. Reg. 69441, 69444 n.11 (2013) (giving no weight to affidavits in which the affiants had relied on hearsay).

I also give little weight to Irelan's testimony concerning his authority to terminate Guidepost Solution's relationship with the Respondent, or to settle lawsuits filed against the

Respondent. Irelan testified that he is the one who would decide to terminate the services of Guidepost. Tr. 803. He then testified that he assumed that "something of this nature would go to the Board." Tr. 804, 837. He also acknowledged that Paul Dickson, Sr., could terminate Guidepost any time he wanted to, or the Board could do so without his input. Tr. 804-05, 840. Irelan also testified that he could sign a settlement on behalf of the Respondent were the company to be sued, but then acknowledged that he had never done so. Tr. 837-39. In short, while Irelan asserted that he had the authority to terminate Guidepost and to settle lawsuits, his follow-up testimony significantly undercut his credibility concerning those assertions. Nevertheless, other than the above exceptions, Irelan's testimony was sufficiently objective, plausible, and internally consistent. Therefore, I merit it as generally credible in this Recommended Decision.

The last witness called by the Respondent was **Louis Milione** ("Milione"). Tr. 841-1057. He is currently the Senior Managing Director of Guidepost Solutions ("Guidepost"), a company that provides consulting services related to compliance issues concerning the Controlled Substances Act. Tr. 842-43. Milione is in charge of that portion of Guidepost's operation. Tr. 843. Paul Dickson, Sr., hired Guidepost in early May 2018. Tr. 844, 1011. Milione has provided similar consulting services to four or five other companies. Tr. 845. Before working for Guidepost, Milione was DEA's Assistant Administrator in the Diversion Control Division for two years. *Id.* Milione spent about 21 years with the DEA starting out as a special agent. Tr. 846. He retired from the DEA in June 2017. Tr. 940-41. As the Assistant Administrator, Milione had programmatic control over the Diversion Control Division. *Id.* The Respondent offered Milione as an expert "in diversion." Tr. 851. There being no objection from the Government, he was so recognized. *Id.*

Milione testified concerning when he first met Paul Dickson, Sr., and about a follow-up meeting Dickson invited him to at the Respondent's facilities in Shreveport, Louisiana. Tr. 852-53. Milione testified about attending the meeting, along with several other DEA employees in August 2016. Tr. 856-57, 941. At the meeting the Respondent discussed its suspicious order monitoring program, utilizing a Power Point presentation. Tr. 861, 864-870, 976, 1013-14.

Milione testified that after DEA issued an ISO to the Respondent, he contacted Paul Dickson, Sr. Tr. 877-78. Shortly thereafter, the Respondent retained Milione's firm, Guidepost, to enhance the Respondent's compliance system, to include its SOM system. Tr. 878-79.

Milione then discussed the work Guidepost has performed for the Respondent, detailing seven areas in which the Respondent's compliance has been improved. Tr. 882-900, 1008-09. In Milione's opinion, the Respondent's reporting of suspicious orders had been insufficient, Tr. 989, and the Respondent should have filed reports concerning pharmacies it had terminated as customers based upon the Respondent's SOM system. Tr. 1015-16.

Having observed Milione's demeanor on the witness stand, and assessing the content of his testimony against other evidence of record, I find his testimony was presented in an objective and unbiased manner. I, however, give no weight to his assessment of the commitment or sincerity of the Respondent's employees concerning their intent to comply with DEA regulations prior to issuance of the OSC. I do so because it is opinion evidence and because intent is not an issue. Further, I give no weight to the Government ethics/conflict-of-interest issue raised by the Government in its cross-examination of Milione. Tr. 945-52. I do so because issues concerning whether Milione needed permission from the DEA to testify in this case, or whether his testimony may have violated regulations or statutes, are not issues before me.

I have assessed Milione's testimony as I would the testimony of any other witness and, despite his interest in the case as a hired consultant to the Respondent, I find that he is a credible witness. I, however, give limited weight to Milione's testimony concerning whether a suspicious order report would be required when a distributor had knowledge that a pharmacy was dispensing controlled substances at a higher rate than the national average, or whether a significant number of its customers were paying cash for controlled substances, or whether a distributor is required to resolve red flags and document its due diligence efforts. I do so because I find his testimony regarding those issues to be inconsistent with published decisions of the DEA.

THE FACTS

I. Stipulations

The Parties agree to **47** stipulations ("Stip."), which are accepted as facts in these proceedings:

1. Respondent is currently registered with the DEA as a distributor in Schedules II through V under DEA Certificate of Registration No. RM0314790 at 10301 Highway 1 South,

Shreveport, Louisiana 71115. [As of the date this stipulation was entered into, t]his Certificate of Registration expire[d] by its own terms on January 1, 2019. ALJ-9; Tr. 10.

2. Respondent, d/b/a Spark Drug, Inc., is currently registered with the DEA as a distributor in Schedules II through V under DEA Certificate of Registration No. RM0335732 at 336 Saint George Avenue, Jefferson, Louisiana 70121. [As of the date this stipulation was entered into, t]his Certificate of Registration expire[d] by its own terms on January 1, 2019. *Id.*

3. Respondent is currently licensed with the Louisiana Board of Drug and Device Distributors under License No. 4299 at 10301 Highway 1 South, Shreveport, Louisiana 71115. [As of the date this stipulation was entered into, t]his license expire[d] by its own terms on December 31, 2018. *Id.*

4. Respondent, d/b/a Spark Drug, Inc., is currently licensed with the Louisiana Board of Drug and Device Distributors under License No. 2015 at 336 Saint George Avenue, Jefferson, Louisiana 70121. [As of the date this stipulation was entered into, t]his license expire[d] by its own terms on December 31, 2018. *Id.*

5. Oxycodone is listed by the DEA as a Schedule II controlled substance. *Id.*

6. Until October 6, 2014, hydrocodone was listed by the DEA as a Schedule III controlled substance. Since October 6, 2014, hydrocodone is listed by the DEA as a Schedule II controlled substance. *Id.*

7. Between January 1, 2014 and May 1, 2018, Respondent submitted a total of three suspicious order reports to the DEA. *Id.*

8. DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), which is an automated system developed and designed to allow DEA to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level. *Id.*

9. Respondent is required to report to the ARCOS system shipments of all controlled substances in Schedule I and II and all narcotic controlled substances in Schedule III. *Id.*

10. Respondent reports its shipments of all controlled substances in Schedule I and II and all narcotic controlled substances in Schedule III to the ARCOS system on a monthly basis. *Id.*

11. From at least October 1, 2017 until at least April 30, 2018, Respondent supplied the Wallace Drug Company (DEA No. FW6006363) with controlled substances, including oxycodone and hydrocodone. *Id.*
12. From at least January 2014 until at least April 30, 2018, Respondent supplied the Bordelon's Super-Save Pharmacy (DEA No. AB6203549) with controlled substances, including oxycodone and hydrocodone. *Id.*
13. From at least January 2014 until at least April 30, 2018, Respondent supplied the Folse Pharmacy (DEA No. BF0636451) with controlled substances, including oxycodone and hydrocodone. *Id.*
14. From at least January 2014 until at least April 29, 2018, Respondent supplied Pharmacy Specialties Group (DEA No. FP4243589) with controlled substances, including oxycodone and hydrocodone. *Id.*
15. From at least January 2014 until at least May 1, 2018, Respondent supplied the Dave's Pharmacy (DEA No. BD5662386) with controlled substances, including oxycodone and hydrocodone. *Id.*
16. From at least April 2017 until May 2017, Respondent supplied Hephzibah Pharmacy LLC (DEA No. AV5145695) with controlled substances, including oxycodone and hydrocodone. ALJ-9; Tr. 10-11.
17. From at least January 2014 until December 2017, Respondent supplied the Wellness Pharmacy (DEA No. BT7485166) with controlled substances, including oxycodone and hydrocodone. ALJ-9; Tr. 10.
18. By letter dated December 16, 2017, the Wellness Pharmacy reported that it had gone out of business and retired its DEA Certificate of Registration. *Id.*
19. From at least January 2014 until April 2017, Respondent supplied the Wilkinson Family Pharmacy (DEA No. FW3669198) with controlled substances, including oxycodone and hydrocodone. *Id.*
20. On April 19, 2017, the Wilkinson Family Pharmacy voluntarily surrendered its DEA Certificate of Registration for cause. *Id.*
21. On November 15, 2017, DEA conducted a periodic audit at Respondent's facilities. *Id.*
22. On February 1, 2018, DEA served an administrative subpoena on Respondent seeking records pertaining to suspicious order reports filed by Respondent as well as records and

documents pertaining to due diligence or internal investigations conducted on possible suspicious orders for controlled substances from January 1, 2016 to February 1, 2018. *Id.*

23. On February 2, 2018, DEA served an administrative subpoena on Respondent seeking records pertaining to the distribution of controlled substances to Wilkinson Family Pharmacy (Registration No. FW3669198) from June 1, 2015 through June 1, 2017. *Id.*

24. On April 11, 2018, DEA served an administrative subpoena on Respondent seeking records reflecting Respondent's policies, guidance, and/or training for its employees with respect to the identification, investigation, and reporting of suspicious or potentially suspicious orders. *Id.*

25. On May 2, 2018, the DEA Acting Administrator issued an Order to Show Cause and Immediate Suspension of Registration (the "ISO") to Respondent, immediately suspending both Registration Nos. RM0314790 and RM0335732. *Id.*

26. On May 18, 2018, the DEA Acting Administrator rescinded the ISO issued on May 2, 2018, to the Respondent's Certificate of Registration numbers RM0314790 and RM0335732. Tr. 12.

27. On May 29, 2014, DEA conducted a periodic audit at Respondent's Shreveport facility. [Proposed] Respondent Exhibit 9 is a true and accurate copy of a Notice of Inspection issued by DEA on May 29, 2014. ALJ-21; Tr. 11. [This exhibit was not offered as evidence.]

28. On October 27, 2015, DEA conducted a periodic audit at Respondent's Shreveport facility. [Proposed] Respondent Exhibit 10 is a true and accurate copy of a Notice of Inspection issued by DEA on October 27, 2015. *Id.* [This exhibit was not offered as evidence.]

29. On November 15, 2017, DEA conducted a periodic audit at Respondent's Shreveport facility. [Proposed] Respondent Exhibit 12 is a true and accurate copy of a Notice of Inspection issued by DEA on November 15, 2017. *Id.* [This exhibit was not offered as evidence.]

30. [Proposed] Government Exhibit 1 is a complete and accurate copy of Respondent's DEA Certificate of Registration No. RM0314790. *Id.* [This exhibit was not offered as evidence.]

31. [Proposed] Government Exhibit 2 is a complete and accurate copy of Respondent's DEA Certificate of Registration No. RM0335732. *Id.* [This exhibit was not offered as evidence.]

32. Government Exhibit 3 is a complete and accurate copy of a letter from the then-Deputy Assistant Administrator, Office of Diversion Control, addressed to all distributor registrants dated September 27, 2006. *Id.*

33. Government Exhibit 4 is a complete and accurate copy of a letter from the then-Deputy Assistant Administrator, Office of Diversion Control, addressed to all distributor registrants dated December 20, 2007. *Id.*

34. [Proposed] Government Exhibit 5 is a true and accurate copy of a letter from the then-Deputy Assistant Administrator, Office of Diversion Control, addressed to all distributor registrants dated June 12, 2012. *Id.* [This exhibit was not offered as evidence.]

35. Government Exhibit 6 is a true and accurate copy of three suspicious order reports submitted by Respondent to DEA, dated April 7, 2014; April 26, 2017; and April 26, 2017. *Id.*

36. Government Exhibit 7 is a true and accurate copy of Administrative Subpoena No. GH-18-326222, issued February 1, 2018 (and certificate of service) served by DEA on Respondent. *Id.*

37. Government Exhibit 8 is a true and accurate copy of Administrative Subpoena No. GH-18-327442, issued February 2, 2018 (and certificate of service) served by DEA on Respondent. *Id.*

38. Government Exhibit 9 is a true and accurate copy of a written response by Respondent to DEA's administrative subpoenas contained in Government Exhibits 7 and 8 and received by DEA on or about February 23, 2018. *Id.*

39. Government Exhibit 10 is a true and accurate copy of an email from David Lemoine to Jacob Dickson, dated March 16, 2018. *Id.*

40. Government Exhibit 11 is a true and accurate copy of Respondent's written response to the email contained in Government Exhibit 10. *Id.*

41. Government Exhibit 12 is a true and accurate copy of an email from Robin Hogue to Jacob Dickson, dated April 4, 2018. *Id.*

42. Government Exhibit 13 is a true and accurate copy of a letter from Paul Dickson to Robin Hogue, dated April 9, 2018. *Id.*

43. Government Exhibit 15 is a true and accurate copy of Administrative Subpoena No. GH-18-531012, issued April 11, 2018 (and certificate of service) served by DEA on Respondent. *Id.*

44. Government Exhibit 16 is a true and accurate copy of a letter from Jacob Dickson to Robin Hogue, dated April 26, 2018. *Id.*

45. Government Exhibit 19 is a true and accurate copy of a letter from Jacob Dickson to the "Agent in charge" of the New Orleans Division received on or about April 27, 2018. *Id.*

46. Respondent Exhibits 20.001 through 20.115 are a complete and accurate recording of flagged orders reported by Respondent to the attention of Joel L. Dunn of the DEA New Orleans Field Division between May 14, 2018 through July 30, 2018. *Id.*

47. Respondent Exhibits 20.001 through 20.115 are records of regular reporting made and transmitted to DEA; the data was kept in the course of a regularly conducted activity at Respondent and it was a regular practice of Respondent to create and transmit these records. *Id.*

II. Findings of Fact

A Distributor's Regulatory Obligations

1. Government Exhibit 3 is a September 27, 2006, letter that the DEA sent to distributors of controlled substances. Tr. 62-63; GE-3, at 1. Respondent received a copy of the letter. Tr. 63. The letter reminded distributors of their "responsibilities . . . in view of the prescription drug abuse problem our nation currently faces." GE-3, at 1. The letter reminded distributors of their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and their duty to report suspicious orders to the DEA upon discovering the suspicious order. *Id.* at 2. In addition, the letter reminded distributors of their duty to exercise due diligence to avoid filling suspicious orders. *Id.* In addition, the letter provided distributors 14 examples of a customer's behavior that might be indicative of diversion. *Id.* at 3. The letter states that these examples are not all-inclusive. *Id.* The same letter was sent a second time on February 7, 2007. Tr. 64-65; GE-69.

2. Government Exhibit 4 is a December 20, 2007, letter that the DEA sent to every distributor of controlled substances. Tr. 63-64; GE-4, at 1. The purpose of this letter was to remind distributors of the requirement to inform the DEA of suspicious orders. GE-4, at 1. The letter reminded distributors that in addition to "maintain[ing] effective controls against diversion," that they are also required to "report suspicious orders of controlled substances." *Id.* The letter instructed that such orders were to be reported "when discovered by the registrant." *Id.* (emphasis in original). The letter also reminded distributors "that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels." *Id.*

3. The DEA maintains an Automation of Reports and Consolidated Orders System ("ARCOS"). Tr. 69-70. Distributors are required to report to ARCOS all shipments of controlled substances in Schedules I and II and all narcotic controlled substances in Schedule III. Stip. 9; Tr. 70.

4. In April 2008, the DEA met with the Respondent (Paul Dickson) and discussed with him the legal obligations and requirements of a distributor, to include suspicious order requirements, the need to know its customers, and the need to do due diligence. Tr. 67-68. At the time, the DEA reviewed the ARCOS data with the Respondent to show them customers who had anomalies. Tr. 68-69.

5. In 2013 and 2015, the DEA conducted distributor conferences and Jacob Dickson attended both conferences. Tr. 66-67. At one conference he was listed as the Respondent's president, and at the other conference he was listed as the Respondent's compliance officer. Tr. 67. The purpose of the conferences was to review laws and regulations. Tr. 66. The conferences included discussions of suspicious order monitoring and the requirement to "know your customer." Tr. 67.

6. As part of its duty to maintain effective controls against diversion, a distributor is required to know its customers. Tr. 57-58. A distributer is required to know the customer's business activity and if the customer has a DEA registration. *Id.*

7. A distributor is required to design and operate a system to detect suspicious orders of controlled substances. Tr. 58; 21 C.F.R. § 1301.74(b). This is a continuous process. *Id.*

8. A distributor is not required to have a new customer fill out a questionnaire, but it would be helpful. Tr. 77. Using a questionnaire would be indicative of a distributor getting to know its customer. Tr. 78.

9. A distributor should check to see which physicians are the high-volume dispensing physicians for a customer pharmacy. Tr. 79-80.

10. A distributor should request the dispensing records of a pharmacy, and review those records. Tr. 80.

11. A distributor should check to see if its customer pharmacies are appropriately licensed. Tr. 81.

12. A suspicious order includes orders of unusual size or frequency, or those deviating from a normal ordering pattern. Tr. 59, 479-80; 21 C.F.R. § 1301.74(b). An order is suspicious if it meets any one of these criteria. Tr. 647. These are not the only criteria, however, that can be used to identify a suspicious order. Tr. 58, 479-80, 647; 21 C.F.R. § 1301.74(b). There are things that would require a distributor to send a suspicious order report to the DEA other than orders of unusual size, pattern, or frequency. Tr. 1033-34.

13. A system for identifying a suspicious order would be insufficient if it only flagged an order based on whether the order exceeded a certain percentage compared to the prior month's order (e.g., ten times more than the prior month). Tr. 321-22, 482, 652; GE-4, at 2.

14. A distributor does not need to believe a suspicious order is being diverted in order to trigger the distributor's obligation to report that order to DEA under 21 C.F.R. § 1301.74(b). Tr. 497-98.

15. The DEA does not endorse any particular system for identifying suspicious orders. Tr. 59-60, 76, 210, 497, 646. A distributor could use a manual system to detect suspicious orders. Tr. 76-77, 497.

16. A distributor is required to notify the DEA upon discovering that an order is suspicious. Tr. 60-61, 85-87, 283, 479, 497, 1024; 21 C.F.R. § 1301.74(b).

17. A distributor should evaluate every individual order at the time it is placed. Tr. 527-28, 546. A distributor, however, cannot compare that order to transactions that have not yet occurred. Tr. 527-28.

18. If through its own due diligence or from a reliable third party, a distributor learns that a pharmacy customer has been filling prescriptions written by a doctor whose DEA registration cannot be verified, and the pharmacy has submitted an order for controlled substances to the distributor, the distributor should submit a suspicious order report to the DEA. Tr. 1025-28.

19. If a distributor receives reliable information that a customer pharmacy is dispensing controlled substances at a higher percentage rate than the national average, the distributor should investigate to determine why the pharmacy's percentage is high. Tr. 1028-33. Milione testified, however, that such information alone would not require the submission of a suspicious order report to the DEA. Tr. 1032-33.

20. In Milione's opinion, if a distributor receives reliable information that a pharmacy customer is filling prescriptions for cash at a higher rate for controlled substances than for non-controlled substances, an order for controlled substances from that pharmacy is not necessarily a suspicious order. Tr. 1036-37.

21. The distributor is obligated to report to DEA a suspicious order even if the distributor resolves the red flags that made the order suspicious. Tr. 480-81.

22. Red flags for distributors include a pharmacy that: dispenses a high volume of narcotics; dispenses the trinity drug cocktail; dispenses disproportionally more controlled substances than non-controlled substances; fills prescriptions for customers who live far away from the pharmacy; fills prescriptions for a high volume of patients who pay for prescriptions in cash; fills prescriptions for practitioners whose DEA registrations cannot be verified; fills a disproportionate volume of controlled substance prescriptions written by only a few prescribers; and orders excessive quantities of a limited variety of controlled substances. Tr. 297, 299-301, 335, 411, 427, 489-90, 648-49, 681, 1037. Weinstein testified that red flags are visible in a pharmacy's dispensing data and not its ordering data. Tr. 679.

23. Distributors should be aware of a pharmacy's relative volume of purchases of controlled versus non-controlled substances. Tr. 648. Fifteen percent[5] is considered the high end in

[5] *But see Masters Pharm., Inc.*, 80 Fed. Reg. 55418, 55480 (2015), *pet. for rev. denied*, *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017) ("[I]n the *Southwood* decision, . . . the Agency had noted that the ratio of controlled to non-controlled substances dispensed by a typical retail pharmacy ranged up to 20 percent for controlled versus 80 to 90 percent for non-controlled drugs." (citing *Southwood Pharm., Inc.*, 72 Fed. Reg. 36487 (2007))];

terms of the percentage of prescriptions that a pharmacy fills that are controlled substances versus non-controlled substances. Tr. 327, 461. Any amount over 15% is a red flag. Tr. 351, 461.

24. Because 9% of the population does not have health insurance, it is a red flag if more than 9% of a pharmacy's controlled substance prescriptions are paid for in cash.[6] Tr. 327-28, 354, 427, 474, 494. Patients engaged in diversion prefer to pay in cash to avoid detection by insurance companies. Tr. 494-95.

25. Oxycodone, hydrocodone, benzodiazepines, and muscle relaxers, such as Soma, are all controlled substances that are sought for illicit use. Tr. 52.

26. A trinity drug cocktail consists of an opioid, such as hydrocodone, a benzodiazepine, such as alprazolam, and a muscle relaxant, such as Soma. Tr. 55, 300. The term, "trinity drug cocktail" is recognized in the registrant community. *Id.* It is still considered a trinity drug cocktail even if each element of the cocktail was prescribed by a different prescriber. Tr. 344.

27. It is a red flag where a prescriber's DEA registration number cannot be verified. Tr. 337-38, 341, 354.

28. A pharmacy's increase in dispensing oxycodone or hydrocodone, without an increase in other drugs, could be a red flag.[7] Tr. 364, 471-72.

29. A distributor should be concerned about a pharmacy that increases its orders for a particular controlled substance when it does not have a similar increase in orders for other medications. Tr. 471-74.

30. The presence of a red flag triggers a distributor's obligation to conduct due diligence. Tr. 295, 298, 301-02, 411, 426-27, 477, 496. When a distributor sees red flags on a Pro-

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Tr. 462. The actual language in *Southwood*, however, is that a witness had testified that "in a typical retail pharmacy, controlled substances might amount to between five and twenty percent of the pharmacy's purchases with the other eighty to ninety (sic) percent of its purchases being non-controlled drugs." 72 Fed. Reg. at 36492. It is not clear from the *Southwood* decision that the "between five and twenty percent" is a factual finding, a legal conclusion, or just a reference to a witness' testimony. In this case, an expert witness testified that anything over 15% would be a red flag. Tr. 351. While that witness later acknowledged the 20% referenced in *Masters*, Tr. 461-62, nothing in this Administrative Record contradicts his expert testimony that anything over 15% would be a red flag. Furthermore, a Pro-Compliance Report stating that 17% "is slightly higher than national averages," GE-21, at 6, lends support to the testimony of the expert that anything over 15% would be a red flag.

[6] *But see* GE-27, at 26 (Pro-Compliance Report stating "cash payments for CS prescriptions (14%) is consistent than (sic) national averages"). Nevertheless, the unrebutted expert testimony in the Administrative Record is that more than 9% is a red flag.

[7] While the testimony was that such an increase could be a red flag, where the increase is significant it is a red flag. Tr. 471-72.

Compliance[8] Report, the distributor is obligated to exercise due diligence in investigating those red flags. Tr. 295, 298, 301-02, 328, 426-27, 474, 484, 492-93.

31. When a distributor receives a Pro-Compliance Report that raises red flags, the distributor should conduct additional due diligence concerning those red flags. Tr. 474.

32. Milione testified that it would not be necessary to resolve all red flags with established customers before shipping controlled substances to a customer, but with new customers red flags should be resolved. Tr. 1038-43, 1051.

33. Even with established customers, if a distributor does not have records to show prior due diligence, a distributor needs to resolve red flags "almost like the new account question." Tr. 1052.

34. A distributor must document the due diligence it conducts. Tr. 298, 302, 465, 474, 484, 493, 1037; *see* Tr. 1041 (Milione testifying that documentation, while not required by regulation, is a best practice). It would be difficult for a distributor to prove that it conducted due diligence if it failed to document the steps it took to resolve a red flag. Tr. 298-99, 302-03, 412, 484.

35. Conducting due diligence of a pharmacy or practitioner could involve visiting a customer's physical location; asking the customer about red flags; looking at open-source information; considering whether the customer specializes in a particular patient population; reviewing a doctor's prescribing patterns; reviewing the percentage of payments that are cash; or reviewing the demographics of a customer, such as its location, proximity to hospitals or surgical centers, and the population it serves. Tr. 392-93, 410-11.

36. As part of its due diligence, a distributor should request customer pharmacies to provide documentation of the pharmacies' efforts to resolve red flags. Tr. 475.

37. It is appropriate for a distributor to ask a pharmacist about a particular prescribing practitioner. Tr. 394.

38. Conducting a second analysis of a pharmacy's dispensing data six months after running the first analysis could be considered additional due diligence. Tr. 421.

[8] The Respondent received Pro-Compliance Reports. Tr. 93, 126. Pro-Compliance is an independent company that provides an analysis of a pharmacy's dispensing. GE-9, at 2.

39. Even if a distributor conducts additional due diligence after identifying red flags, a distributor may not ship an order for controlled substances unless all the red flags have been resolved. Tr. 302, 328, 471, 476, 484. It would not be proper to ship an order of controlled substances before resolving all red flags. Tr. 302, 471. For example, if a distributor identifies that a customer pharmacy is dispensing an unusually high volume of oxycodone, the distributor should conduct due diligence to ensure those prescriptions are "going to a legitimate medical purpose." Tr. 298.

40. If a customer's Pro-Compliance Report for one month raises red flags, and then the next month the customer places an order for controlled substances that is not suspicious in and of itself, a distributor should not ship that order unless the red flags from the previous month's Pro-Compliance Report have been resolved. Tr. 477-78. In other words, red flags from one month do not necessarily render an order made the following month suspicious, but a distributor is still obligated to resolve prior red flags before shipping future orders of controlled substances, even if those orders are not suspicious. Tr. 477-78.

41. It is appropriate for a distributor to provide a pharmacy with an analysis of the pharmacy's dispensing, such as Pro-Compliance Reports, and to discuss red flags with the pharmacy. Tr. 393-94, 449.

42. A distributor is not to ship an order that it has identified as suspicious if it is not able to resolve the concern about why the order was thought to be suspicious. Tr. 61-62, 85, 294.

43. If the distributor fails to report a suspicious order, DEA has "no way of knowing it occurred" and cannot investigate that order. Tr. 283-84, 498.

DEA's Investigation of Respondent & Respondent's Response to DEA Subpoenas

44. In 2017, the DEA in New Orleans was looking into pharmacies in Louisiana that sold high volumes of oxycodone and hydrocodone. Tr. 92. A common denominator of some of those pharmacies was that the Respondent was their supplier. *Id.* The DEA then conducted a cyclical audit of the Respondent, which lasted two days. Tr. 92-93.

45. During the cyclical audit, the Respondent informed DEA that it used a company called Pro-Compliance to help identify suspicious orders. Tr. 93. The Respondent also stated

that it relied on its employees who filled the orders and on its drivers who delivered the orders to help identify suspicious orders. *Id.*

46. The DEA served the Respondent with a subpoena, dated February 1, 2018, seeking the Respondent's documentation concerning any suspicious order reports it filed, and any documentation concerning its due diligence efforts or internal investigations conducted on possible suspicious orders from January 1, 2016, to February 1, 2018. Tr. 96-97; GE-7.

47. The DEA served the Respondent with a subpoena, dated February 2, 2018, seeking the Respondent's records pertaining to the distribution of controlled substances to Wilkinson Family Pharmacy, to include due diligence files, from June 1, 2015, through June 1, 2017. Tr. 98-99; GE-8.

48. In response to the DEA's February 2018 subpoenas, the Respondent sent an undated letter to DEA. GE-9; Tr. 99, 318. The letter was signed by Jacob Dickson, who identified himself as the Respondent's Vice President and suspicious order monitoring ("SOM") Manager. GE-9, at 5.

49. The undated letter states that the Respondent submitted only two suspicious order reports to DEA because it "utilizes a pro-active approach to avoid diversion of controlled drugs, including: screening new pharmacy customers; aggressively monitoring orders for controlled drugs; and eliminating pharmacy customers who fill orders for controlled drugs in excess of acceptable ratios, accept cash payments, prescribe the 'Holy Trinity' and/or other unacceptable practices." GE-9, at 1; Tr. 319.

50. The undated letter also states that "DEA and applicable regulations do not require that a wholesale distributor maintain records of each and every internal investigation conducted on possible suspicious orders." GE-9, at 1-2 (emphasis in original); Tr. 319-20. In Dunn's opinion, this statement does not comply with what DEA requires of distributors because DEA has case law establishing that distributors are required to keep records of its investigations into suspicious orders. Tr. 320. Specifically, Dunn stated that the *Masters*[9] and *Southwood*[10] Final Orders stand for the proposition that distributors are required to maintain records of suspicious order investigations. Tr. 320. The letter

[9] *Masters Pharm., Inc.*, 80 Fed. Reg. 55418 (2015), *pet. for rev. denied*, 861 F.3d 206 (D.C. Cir. 2017).
[10] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36487 (2007).

further explained that once the Respondent had cleared a possible suspicious order, "no record is maintained." GE-9, at 2.

51. The undated letter explained that the Respondent used a "four-fold approach to monitor all prescription drug orders and detect unusual ordering patterns, amounts, and cash payments to identify potentially suspicious orders." GE-9, at 2; Tr. 321. The four-fold approach included: use of Pro-Compliance Reports; preparing a Market Basket Report of each customer on a monthly basis; since April 2017 use of software that identifies orders that are more than 10 times the "average dosage units ordered on a given drug on a certain day with the last 90 days of ordering patterns of the same drug"; the experience of the employees who fill the orders for controlled substances; and the input of delivery drivers and salesmen. GE-9, at 3-4.

52. The undated letter says that the Respondent has an excessive order prevention software program in a beta-testing stage that is designed to identify orders of controlled substances that are 10 times the average. GE-9, at 3; Tr. 321. Identifying orders that are 10 times the average is arbitrary, and an order could be suspicious if it were 8 or 9 times the average. Tr. 322, 482.

53. The undated letter says that "[o]n-the-ground employees often submit photos of the premises and photos of the store owner to the Compliance Officer." GE-9, at 4; Tr. 322. In the documents the Respondent produced to DEA, Dunn did not see any photographs. Tr. 322, 439.

54. The undated letter describes three potentially suspicious orders identified by the Respondent's Compliance Officer that the Respondent stated were ultimately determined to be not suspicious. GE-9, at 4. The letter also mentions examples of pharmacies "mistakenly keying incorrectly high order quantities." GE-9, at 4. The letter says that in each example the Compliance Officer "spoke to the pharmacist" and "corrected the order before shipment." GE-9, at 4. This policy does not comply with DEA regulations and these orders should have been reported to DEA. Tr. 323, 478-79. This policy does not comply with DEA regulations because if a pharmacy places a suspicious order, the distributor cannot avoid its obligation to report suspicious orders simply based on the pharmacy's claim that it made a mistake. Tr. 478-79. If the distributor investigates the

claim and believes the pharmacy made a mistake, the distributor may ship the order but still must report to DEA the fact that the order appeared suspicious. Tr. 479.

55. The undated letter states that "[i]n the past decade, [Morris & Dickson] has ceased supplying 142 retail pharmacies due to questions and concerns that the pharmacies were over-dispensing controlled substances." GE-9, at 5; Tr. 470. The letter further asserted that after it had closed these bad accounts it had "seen very few examples which would justify the reporting of a suspicious order. In most cases, when a potentially suspicious order is investigated, there is a justifiable reason for the order." GE-9, at 5. The Respondent did not provide documentation of those reasons.

56. During the cyclical audit, the DEA asked the Respondent to produce copies of suspicious order reports it had made to the DEA. Tr. 94. The Respondent provided the DEA with two reports of suspicious orders, both dated April 26, 2017. *Id.*; GE-6, at 35-36. Although the reports concern two different pharmacies, the Respondent listed the same DEA number on each report. *Id.* Earlier, the Respondent submitted a suspicious order report to the DEA, dated, April 7, 2014. Tr. 95; GE-6, at 1-34. Only one of the reports details why the Respondent considered an order to be suspicious. GE-6, at 35. That report details that the pharmacy had submitted an order for 60 cartons of prefilled morphine syringes, when it had only ordered 1 carton during the previous 4 months. *Id.*

57. During the investigation, the DEA requested the Respondent to produce its due diligence files. Tr. 96-97, 295; GE-7, at 1.

58. The Respondent produced some due diligence files in response to DEA's subpoenas. Tr. 295, 463.

59. The documentation the Respondent produced to the DEA does not show whether the Respondent resolved red flags concerning orders it had received from pharmacy customers. Tr. 413.

60. The Respondent shared its Pro-Compliance Reports with its customer pharmacies. Tr. 449.

61. By email, dated March 16, 2018, the DEA sought clarification of the Respondent's reply to the subpoenas of February 1 and 2, 2018. Tr. 100-01; GE-10. The DEA sought clarification of whether the Respondent had fully responded to the subpoena concerning Wilkinson Family Pharmacy and provided all records it had concerning due diligence or

internal investigations from January 1, 2016, to "present." GE-10, at 1. Additionally, the DEA March email requested that the Respondent produce any records concerning due diligence or investigations with respect to 11 pharmacies the Respondent had identified to the DEA. *Id.* Finally, the DEA sought information and records concerning 16 pharmacies the Respondent had identified, specifically asking how the pharmacies were identified through the Respondent's system.[11] *Id.* at 2.

62. Government Exhibit 11 is a supplemental response from the Respondent to subpoenas issued by the DEA. Tr. 144-45, 324. The response is not dated and is signed by Paul Dickson. Tr. 145; GE-11, at 2. This letter says that "[b]ecause formal records are not kept in the regular course of business on the investigation of orders which do not result in the finding of a 'suspicious order' per 21 C.F.R. 1301.74, the email communications produced herewith represent the most responsive records maintained." GE-11, at 2; Tr. 324. At the same time, the Respondent also produced an external hard drive containing documents in response to the February subpoenas. Tr. 146.

63. The undated response also indicates that the Respondent provided DEA with delivery receipts for all orders to Wilkinson Family Pharmacy, as well as "every Market Basket Report and Pro Compliance Report in its records from January 1, 2016 to the present." GE-11, at 1. The undated response also informed the DEA that "[d]uring the normal course of business, excessive orders which are the result of coding mistakes are dealt with promptly via telephone and such incidents are usually not documented." *Id.* The response also indicated that the Respondent's SOM program resulted in several investigations based on a software alert, review of Pro-Compliance and Market Basket Reports, as well as concerns raised by the Respondent's employees. *Id.* The Respondent also noted that prior to receipt of the DEA subpoenas the Respondent conducted investigations of "unusual or potentially suspicious orders via telephone calls . . . and by salesman in-store calls." *Id.* at 2.

64. In the materials the Respondent produced to DEA, Dunn did not see any evidence of orders that were identified as suspicious and therefore not shipped before the issuance of the OSC/ISO. Tr. 325-26.

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[11] The Administrative Record does not identify the names of the 11 and 16 pharmacies the DEA referred to in Government Exhibit 10.

65. In the documents the Respondent produced to DEA, Dunn did not recall seeing any screenshots of the electronic customer profile that the Respondent had in place at that time. Tr. 439-40.

66. Following receipt of Government Exhibit 11, on April 4, 2018, the DEA sent an email to the Respondent to determine if the Respondent believed it had fully complied with the DEA subpoenas of February 1 and 2, 2018. Tr. 147; GE-12.

67. In response to the DEA's April 4, 2018 email, the Respondent sent a letter to the DEA on April 9, 2018. Tr. 148; GE-13. In the Respondent's letter, Paul Dickson informed the DEA that the Respondent believed that it had provided a full response to the subpoenas, but that it could not "unconditionally confirm that there are no other documents . . . ." GE-13, at 1. In addition, the Respondent provided a phone log that detailed conversations between the Respondent's compliance officer, Clara Guin, "some of which may relate to the subject of [the] subpoena request" concerning suspicious order reports and investigations. *Id.* Government Exhibit 14 is a copy of that phone log. Tr. 149-50.

68. The phone log is 33 pages long, with the earliest entry dated January 5, 2016, and the most recent entry dated February 28, 2018. GE-14, at 1, 33. The phone log contains 14 entries that relate to some of the exemplar pharmacies mentioned in the OSC.[12] GE-14, at 4, 23, 24, 26, 31.

69. The DEA served the Respondent with a subpoena, dated April 11, 2018, seeking the Respondent's documents pertaining to its "policies, guidance, and/or training for its employees with respect to the identification, investigation, and reporting of suspicious or potentially suspicious orders of controlled substances." Tr. 172-73; GE-15, at 1.

70. On April 26, 2018, the Respondent replied to the DEA subpoena of April 11, 2018. Tr. 173-74; GE-16. In its reply, the Respondent informed DEA that its training of employees on suspicious order monitoring "does not necessitate or result in the production of documents." GE-16, at 1. The Respondent's reply included two policy

[12] There are two entries concerning the Pharmacy Specialties Group, with a DEA number ending in "589." GE-14, at 4, 31; GE-23, at 1. Those entries are dated March 7, 2016, and December 13, 2017. GE-14, at 4, 31. There is one entry concerning Dave's Pharmacy, with a DEA number ending in "386." GE-14, at 23; GE-24, at 1. That entry is dated February 16, 2017. GE-14, at 23. There are three entries concerning Hephzibah Pharmacy, with a DEA number ending in "695." GE-14, at 23, 26; GE-25, at 1. Those entries are dated March 17 and 21, 2017, and June 20, 2017. GE-14, at 23, 26. There are five entries concerning Wilkinson Family Pharmacy, with a DEA number ending in "198." GE-14, at 24; GE-27, at 1. Those entries are dated April 19, 20, 21, and 24, 2017. GE-14, at 24. There are three entries concerning Wallace Drugs, with a DEA number ending in "363." GE-14, at 31; GE-20, at 1. Those entries are all dated January 9, 2018. GE-14, at 31.

and procedure documents that contain "limited direction as to suspicious order monitoring." *Id.* Those documents were the Respondent's "Policies & Procedures Manual," and its "Standard Operating Procedures Manual." Tr. 174-76; GE-17-18.

Pro-Compliance Reports & Market Basket Analysis Reports

71. Pro-Compliance Reports are an analysis of a pharmacy's dispensing data created by Pro-Compliance. Tr. 464-65, 716-17. The reports list key indicators of red flags of diversion, such as percentage of a customer's business that is controlled substances, volume of cash payments, and the amount of trinity drug cocktails. Tr. 716-17.

72. Each Pro-Compliance Report contains the following statement, or a similar statement: "Since the passage of the Controlled Substances Act, emphasis has been placed on Manufacturers and Distributors, registered with DEA, to design and operate a system that will disclose suspicious orders of controlled substances and regulated chemical products by their customers. The responsibilities by DEA registered Manufacturers and Distributors is to assure DEA that all purchased and dispensed controlled substances and regulated chemical products are for legitimate use. The responsibility is not only for their customer but also their customer's customers." GE-23, at 11; Tr. 355.

73. The Pro-Compliance Report provides a meaningful tool for the Respondent, but Milione did not find the DEA verification portion of the Pro-Compliance Report to be reliable.[13] Tr. 900-04, 955-56. Milione found that there were many false positives in the DEA verification section of the Pro-Compliance Reports and the Respondent could not rely on it in any meaningful way. Tr. 956-57. Milione has discussed this matter with Pro-Compliance. Tr. 901. Milione had no reason "to doubt the reliability of the rest of the reports." Tr. 957.

74. Government Exhibit 20 contains the Respondent's client account profile for Wallace Drug, as well as a Pro-Compliance Report concerning that pharmacy. Tr. 151-52; GE-20, at 1, 4.

[13] Both Irelan and Milione testified that the portion of the Pro-Compliance Reports concerning the verification of prescriber DEA numbers is unreliable. Tr. 765-66, 797, 901. Irelan had nothing to do with compliance issues on behalf of the Respondent until May 2018, and Milione was retained as a consultant by the Respondent in the same month. Tr. 699, 844. Thus, there is no evidence in the Administrative Record that before May 2018 the Respondent considered the information in the Pro-Compliance Reports concerning the verification of prescriber DEA numbers to be unreliable.

75. Government Exhibit 57 is a Market Basket Analysis Report ("Market Basket Report") concerning Wallace Drug that the Respondent provided to the DEA in response to the February 2018 administrative subpoenas. Tr. 162-63; GE-57.

76. Government Exhibit 21 contains the Respondent's client account profile for Bordelon's, as well as a Pro-Compliance "Initial Risk Evaluation," and a Pro-Compliance Report concerning that pharmacy. Tr. 153-54; GE-21, at 1, 4, 13.

77. Government Exhibit 58 is a Market Basket Report concerning Bordelon's that the Respondent provided to the DEA in response to the February 2018 administrative subpoenas. Tr. 164-66; GE-58.

78. Government Exhibit 22 contains the Respondent's client account profile for Folse, as well as Pro-Compliance "Initial Risk Evaluations," and Pro-Compliance Reports concerning that pharmacy. Tr. 154-55; GE-22, at 1, 3, 8, 15, 24.

79. Government Exhibit 59 is a Market Basket Report concerning Folse that the Respondent provided to the DEA in response to the February 2018 administrative subpoenas. Tr. 164-66; GE-59.

80. Government Exhibit 23 contains the Respondent's client account profile for Pharmacy Specialties, as well as a Pro-Compliance "Initial Risk Evaluation," and Pro-Compliance Reports concerning that pharmacy. Tr. 155-56; GE-23, at 1, 4, 13, 15, 17.

81. Government Exhibit 60 is a Market Basket Report concerning Pharmacy Specialties that the Respondent provided to the DEA in response to the February 2018 administrative subpoenas. Tr. 164-66; GE-60.

82. Government Exhibit 24 contains the Respondent's client account profile for Dave's Pharmacy, as well as Pro-Compliance "Initial Risk Evaluations," and Pro-Compliance Reports concerning that pharmacy. Tr. 157; GE-24, at 1, 4, 15, 22, 31.

83. Government Exhibit 61 is a Market Basket Report concerning Dave's Pharmacy that the Respondent provided to the DEA in response to the February 2018 administrative subpoenas. Tr. 164-66; GE-61.

84. Government Exhibit 25 contains the Respondent's client account profile for Hephzibah Pharmacy, as well as a Pro-Compliance "Initial Risk Evaluation," and a Pro-Compliance Report concerning that pharmacy. Tr. 158-59; GE-25, at 1, 4, 13.

85. Government Exhibit 62 is a Market Basket Report concerning Hephzibah Pharmacy that the Respondent provided to the DEA in response to the February 2018 administrative subpoenas. Tr. 164-66; GE-62.

86. Government Exhibit 26 contains Pro-Compliance "Initial Risk Evaluations," and a Pro-Compliance Report concerning The Wellness Pharmacy that the Respondent provided to the DEA. Tr. 159-60; GE-26, at 1, 8, 13.

87. Government Exhibit 63 is a Market Basket Report concerning The Wellness Pharmacy that the Respondent provided to the DEA in response to the February 2018 administrative subpoenas. Tr. 164-66; GE-63.

88. Government Exhibit 27 contains the Respondent's client account profile for Wilkinson, as well as Pro-Compliance "Initial Risk Evaluations," and Pro-Compliance Reports concerning that pharmacy. Tr. 161-62; GE-27, at 1, 3, 17, 24, 33.

89. Government Exhibit 64 is a Market Basket Report concerning Wilkinson that the Respondent provided to the DEA in response to the February 2018 administrative subpoenas. Tr. 164-66; GE-64.

Folse Pharmacy

90. Government Exhibit 22 contains the Pro-Compliance Reports for Folse Pharmacy. GE-22; Tr. 328. Included in those reports is an Initial Risk Evaluation Report. GE-22, at 3-11. That evaluation informed the Respondent that Folse represented a "***high risk.***" *Id.* at 5 (emphasis in original). It also revealed that in September 2013, 33% of all the prescriptions filled by Folse were for controlled substances, and 41% of those prescriptions were paid for in cash. GE-22, at 7; Tr. 328-29.

91. A second Pro-Compliance Report for the period from November 1, 2014 to November 29, 2014, informed the Respondent that 36% of all the prescriptions filled by Folse were for controlled substances, and of those prescriptions, 47% were for Schedule II drugs. GE-22, at 12; Tr. 330. It is a red flag whenever the percentage of controlled substances is over 15 percent. Tr. 327, 329, 351.

92. From November 1, 2014 to November 29, 2014, 41% of all controlled substance prescriptions filled by Folse were paid for in cash. GE-22, at 12; Tr. 330. It is a red flag whenever more than 9% of prescriptions for controlled substances are paid for in cash. Tr. 327-28, 330, 354.

93. Between September 2013 and November 2014, the number of oxycodone dosage units dispensed by Folse increased from 40,812 to 52,571. GE-22, at 12; Tr. 330-31. This is a "very big" red flag. Tr. 331; *see also* Tr. 471-74.

94. When the Respondent received a Pro-Compliance Report concerning Folse for November 2014, which showed an increase of almost 12,000 dosage units of oxycodone and that Folse's customers paid cash for 41% of their controlled substances, the Respondent should have determined why there was an increase of oxycodone and why the percentage of cash payments for controlled substances was so high. Tr. 474-75; GE-22, at 12.

95. From January 2, 2016 to January 30, 2016, 35% of all the prescriptions filled by Folse were for controlled substances and of those prescriptions, 46% were for Schedule II drugs. GE-22, at 13; Tr. 331-33.

96. From January 2, 2016 to January 30, 2016, 31% of all controlled substance prescriptions filled by Folse were paid for in cash. GE-22, at 13; Tr. 333-34.

97. In September 2016, 33% of all the prescriptions filled by Folse were for controlled substances and of those prescriptions, 50% were for Schedule II drugs. GE-22, at 14; Tr. 334.

98. In September 2016, 18% of all controlled substance prescriptions filled by Folse were paid for in cash. GE-22, at 14; Tr. 335.

99. In September 2016, Folse dispensed 22 trinity drug cocktails. GE-22, at 14; Tr. 335. A pharmacy filling any prescriptions for a trinity drug cocktail is a red flag. Tr. 300, 335, 353.

100. A Pro-Compliance Report for June 2017, shows that 30% of all the prescriptions filled by Folse were for controlled substances and of those prescriptions, 49% were for Schedule II drugs. GE-22, at 16; GE-35, at Summary tab; Tr. 335. That Pro-Compliance Report also recommended that the Respondent talk with Folse, to "gain a better understanding of [its] dispensing practices," and that a site visit might be "prudent." GE-22, at 17.

101. In June 2017, 26% of all controlled substance prescriptions filled by Folse were paid for in cash. GE-22, at 16; Tr. 336. In addition, the number of dosage units of oxycodone and hydrocodone that Folse dispensed were both higher than the national average. GE-22, at 17.

102. In June 2017, Folse dispensed 9 trinity drug cocktails. GE-22, at 17; Tr. 336.

103. In June 2017, Folse filled prescriptions for 23 practitioners whose DEA registrations could not be verified through "DEA-Verify.com." GE-22, at 17; Tr. 336. This is a red flag. Tr. 336-37, 341.

104. A Pro-Compliance Report for Folse indicates that Folse filled prescriptions in June 2017 for 194 practitioners whose DEA registrations could not be verified.[14] GE-35, at Summary tab; Tr. 337.

105. The Market Basket Report for Folse indicates that 51% of all the prescriptions filled by Folse in January 2016 were for controlled substances. GE-59, at 1; Tr. 338.

106. The Market Basket Report for Folse indicates that 44% of all the prescriptions filled by Folse in March 2017 were for controlled substances. GE-59, at 29; Tr. 338-39.

107. The Market Basket Report for Folse indicates that 42% of all the prescriptions filled by Folse in December 2017 were for controlled substances. GE-59, at 47; Tr. 339.

108. There is no evidence in the Administrative Record that the Respondent suspended any shipments of controlled substances to Folse. Tr. 340.

Bordelon's Super-Save Pharmacy

109. A Pro-Compliance Report for Bordelon's indicates that 17% of all the prescriptions filled by Bordelon's in March 2017 were for controlled substances, that 30% of those prescriptions were in the hydrocodone family, and that 63% were Schedule II drugs. GE-21, at 5-6, 12; Tr. 340-41. In addition, the number of dosage units of oxycodone and hydrocodone that Bordelon's dispensed were both higher than the national average. GE-21, at 6.

110. In March 2017, Bordelon's filled prescriptions for 41 practitioners whose DEA registrations could not be verified. GE-21, at 6; Tr. 341.

111. In March 2017, Bordelon's filled prescriptions for 702 practitioners whose DEA registrations could not be verified.[15] GE-29, at Summary tab; Tr. 342-43.

112. In March 2017, Bordelon's dispensed 4 trinity drug cocktails. GE-21, at 6; Tr. 341.

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[14] While the "Summary" tab of this report indicates there were 194 practitioners who could not be verified, the "DEA Concern" tab of the same report, lists only 23 names. GE-35, at Summary tab and DEA Concern tab. Thus, the "DEA Concern" tab is consistent with the number reported in the paper copy of the Pro-Compliance Report for the same time period. *See* GE-22, at 17; GE-35, at DEA Concern tab.

[15] While the "Summary" tab of this report indicates there were 702 practitioners who could not be verified, the "DEA Concern" tab of the same report lists only 41 names. GE-29, at Summary tab and DEA Concern tab. Thus, the "DEA Concern" tab is consistent with the number reported in the paper copy of the Pro-Compliance Report for the same time period. *See* GE-21, at 6; GE-29, at DEA Concern tab.

113. From September 1, 2017 to an uncertain date in 2017, 17% of all the prescriptions filled by Bordelon's were for controlled substances. GE-21, at 18; Tr. 341-42.

114. A Pro-Compliance Report for Bordelon's indicates that in September 2017, Bordelon's filled prescriptions for 618 practitioners whose DEA registrations could not be verified. GE-30, at Summary tab; Tr. 345-46. The "DEA Concern" tab of the same report, however, lists only 35 names, as does the paper copy of the same report. GE-30, at DEA Concern tab; GE-21, at 19.

115. Government Exhibit 58 shows that the Respondent ran monthly Market Basket Analyses for Bordelon's from January 2016 through January 2018. GE-58; Tr. 423.

116. The Pro-Compliance Report recommended that the Respondent talk with Bordelon's to "gain a better understanding of [its] dispensing practices," and that a site visit might be "prudent." GE-21, at 6. There is no evidence in the Administrative Record that the Respondent followed up on those recommendations or that it suspended any shipments of controlled substances to Bordelon's. Tr. 347-48.

Wallace Drug Company

117. A Pro-Compliance Report for Wallace indicates that 31% of all controlled substance prescriptions filled by Wallace in August 2017 were paid for in cash. GE-20, at 5; Tr. 348.

118. In August 2017, the amount of dosage units of hydrocodone and oxycodone that Wallace dispensed were higher than national averages. GE-20, at 5-6; Tr. 349. This is a red flag. Tr. 349.

119. In August 2017, Wallace filled prescriptions for 23 practitioners whose DEA registrations could not be verified. GE-20, at 6; Tr. 349.

120. A Pro-Compliance Report for Wallace indicates that in August 2017 Wallace filled prescriptions for 623 practitioners whose DEA registrations could not be verified. GE-28, at Summary tab; Tr. 350. The "DEA Concern" tab of the same report lists only 23 names, as does the paper copy of the same report. GE-28, at DEA Concern tab; GE-20, at 6, 13.

121. In August 2017, Wallace dispensed 3 trinity drug cocktails. GE-20, at 5-6; GE-28, at Trinity tab; Tr. 349-50.

122. A Market Basket Report for Wallace indicates that 23% of all the prescriptions filled by Wallace in October 2017 were for controlled substances. GE-57, at 1; Tr. 351.

123. A Market Basket Report for Wallace indicates that 28% of all the prescriptions filled by Wallace in November 2017 were for controlled substances. GE-57, at 3; Tr. 351.

124. A Market Basket Report for Wallace indicates that 37% of all the prescriptions filled by Wallace in December 2017 were for controlled substances. GE-57, at 5; Tr. 352.

125. A Market Basket Report for Wallace indicates that 28% of all the prescriptions filled by Wallace in January 2018 were for controlled substances. GE-57, at 7; Tr. 352-53.

126. The August 2017 Pro-Compliance Report recommended that the Respondent talk with Wallace "[t]o gain a better understanding of [its] dispensing practices," and that a site visit might be "prudent." GE-20, at 6. Other than a phone log entry on January 9, 2018, however, there is no evidence in the Administrative Record that the Respondent suspended any shipments of controlled substances to Wallace. Tr. 353; GE-14, at 31.

Pharmacy Specialties Group

127. A Pro-Compliance Report for Pharmacy Specialties indicates that 24% of all the prescriptions filled by Pharmacy Specialties in February 2016 were for controlled substances and of those prescriptions, 54% were for Schedule II drugs. GE-23, at 5; GE-36, at Summary tab; Tr. 353-54. In October 2016 the percentage of controlled substances had fallen to 18%, but in September 2017 the percentage had risen to 30%, but the percentages of those prescriptions that were Schedule II drugs were 53% and 62%, respectively. GE-23, at 16, 18; GE-37, at Summary tab; GE-38, at Summary tab.

128. A Pro-Compliance Report for February 2016 indicates that 28% of all controlled substance prescriptions filled by Pharmacy Specialties were paid for in cash. GE-23, at 5-6; GE-36, at Summary tab; Tr. 354, 360. That same report recommended that the Respondent have a conversation with Pharmacy Specialties "[t]o gain a better understanding of [its] dispensing practices" and that an "on-site visit to discuss concerns may also be prudent." GE-23, at 6.

129. In February 2016, Pharmacy Specialties filled prescriptions for three practitioners whose DEA registrations could not be verified. GE-23, at 6; Tr. 354.

130. A Pro-Compliance Report for Pharmacy Specialties indicates that Pharmacy Specialties filled prescriptions in February 2016 for 12 practitioners whose DEA registrations could

not be verified. GE-36, at Summary tab; Tr. 359. The "DEA Concern" tab of the same report, however, lists only 3 names, as does the paper copy of the same report. GE-36, at DEA Concern tab; GE-23, at 6, 14; Tr. 354.

131. Government Exhibit 23 reveals that Pharmacy Specialties had filled prescriptions for three practitioners whose DEA registration numbers could not be verified. GE-23, at 14. In fact, one of the numbers began with one letter, a "W," which indicates it was an application for registration that had not yet been approved by DEA. GE-23, at 14; Tr. 356-57; *see also* GE-23, at 19.

132. In February 2016, Pharmacy Specialties dispensed 2 trinity drug cocktails. GE-23, at 6; Tr. 355.

133. In October 2016, 27% of all controlled substance prescriptions filled by Pharmacy Specialties were paid for in cash. GE-23, at 16; GE-37, at Summary tab; Tr. 357-58, 360-61.

134. A Pro-Compliance Report for Pharmacy Specialties indicates that Pharmacy Specialties filled prescriptions in October 2016 for 16 practitioners whose DEA registrations could not be verified. GE-37, at Summary tab; Tr. 360. The "DEA Concern" tab of the same report, however, lists only 2 names that could not be verified. GE-37, at DEA Concern tab.

135. Pharmacy Specialties dispensed 1 trinity drug cocktail in October 2016 and 2 trinity drug cocktails in September 2017. GE-23, at 16, 18; Tr. 358-59.

136. From February 2016 to October 2016, the number of dosage units of hydrocodone dispensed by Pharmacy Specialties increased 25 percent. GE-23, at 16; Tr. 358.

137. A Pro-Compliance Report for Pharmacy Specialties indicates that 31% of all controlled substance prescriptions filled by Pharmacy Specialties from September 1, 2017 to an uncertain date were paid for in cash. GE-23, at 18; Tr. 358.

138. From October 2016 to September 2017, the number of dosage units of oxycodone, hydrocodone, and benzodiazepines dispensed by Pharmacy Specialties increased 148%, 89%, and 106%, respectively. GE-23, at 18; Tr. 358-59. During this same period, however, the total number of prescriptions the pharmacy dispensed decreased by 1 percent. GE-23, at 18.

139. A Market Basket Report for Pharmacy Specialties indicates that 52% of all the prescriptions filled by Pharmacy Specialties in January 2016 were for controlled substances. GE-60, at 1; Tr. 361.

140. A Market Basket Report for Pharmacy Specialties indicates that 38% of all the prescriptions filled by Pharmacy Specialties in October 2017 were for controlled substances. GE-60, at 43; Tr. 361.

141. A Market Basket Report for Pharmacy Specialties indicates that 27% of all the prescriptions filled by Pharmacy Specialties in November 2017 were for controlled substances. GE-60, at 45; Tr. 361-62.

142. While the Respondent's employees apparently raised concern on March 7, 2016, and on December 13, 2017, about orders for controlled substances that Pharmacy Specialties had placed, there is no evidence in the Administrative Record that the Respondent suspended any shipments of controlled substances to Pharmacy Specialties. Tr. 362; GE-14, at 4, 31.

Dave's Pharmacy

143. A Pro-Compliance Report for Dave's, concerning March 2014, identifies several concerns regarding Dave's. GE-24, at 5-6; Tr. 362-63. Those concerns include the statistic that 20% of all the prescriptions filled by Dave's were for controlled substances. *Id.* Those concerns also include the fact that Dave's has filled prescriptions written by practitioners with 85 instances of trinity drug cocktails. *Id.* The Pro-Compliance Report classifies Dave's as "relatively ***high risk*** to Morris & Dickson." GE-24, at 6 (emphasis in original). This same report advised the Respondent that the quantity of hydrocodone that Dave's dispensed was "significantly high," and it encouraged the Respondent to discuss the concerns addressed in the report with Dave's and that an on-site visit "may also be prudent." *Id.*

144. From March 3, 2014 to March 31, 2014, 35% of all controlled substance prescriptions filled by Dave's were paid for in cash. GE-24, at 5; Tr. 363.

145. From January 2, 2015 to January 30, 2015, 22% of all the prescriptions filled by Dave's were for controlled substances, and of those prescriptions, 42% were for Schedule II drugs. GE-24, at 18; Tr. 364.

146. From January 2, 2015 to January 30, 2015, 35% of all controlled substance prescriptions filled by Dave's were paid for in cash. GE-24, at 18; Tr. 364.

147. From March 2014 to January 2015 the number of dosage units of oxycodone that Dave's dispensed increased from 17,889 to 29,994, a significant increase. GE-24, at 18; Tr. 364; *see also* Tr. 380, 471-74.

148. Between March 2014 and January 2015, Dave's dispensed 57 trinity drug cocktails. GE-24, at 18; Tr. 364.

149. In December 2015, 22% of all the prescriptions filled by Dave's were for controlled substances, and of those prescriptions, 45% were for Schedule II drugs. GE-24, at 19; Tr. 365.

150. In December 2015, 28% of all controlled substance prescriptions filled by Dave's were paid for in cash. GE-24, at 19; Tr. 365.

151. Between January 2015[16] and December 2015, Dave's dispensed 27 trinity drug cocktails. GE-24, at 19; Tr. 365.

152. Between January 2015 and December 2015, the number of dosage units of oxycodone that Dave's dispensed increased 205 percent. GE-24, at 19; Tr. 365-66. This is a significant concern. Tr. 366.

153. In June 2016, 23% of all the prescriptions filled by Dave's were for controlled substances. GE-24, at 20; Tr. 366.

154. In June 2016, 28% of all controlled substance prescriptions filled by Dave's were paid for in cash. GE-24, at 20; Tr. 366.

155. Between December 2015 and June 2016, Dave's dispensed 33 trinity drug cocktails. GE-24, at 20; Tr. 366.

156. In November 2016, 22% of all the prescriptions filled by Dave's were for controlled substances, and 17% were purchased using cash. GE-24, at 21; Tr. 367.

157. Between June and November 2016, the number of dosage units of oxycodone that Dave's dispensed increased 14 percent. GE-24, at 21; Tr. 367. This is a red flag. Tr. 367.

158. Between June and November 2016, Dave's dispensed 37 trinity drug cocktails. GE-24, at 21; Tr. 367.

[16] Although the Pro-Compliance Report reads "May 2014," this is likely a typographical error. Typically, by observation, the Pro-Compliance Reports compare data from the date of the previous report, which was January 2015. GE-24, at 18-19.

159. In June 2017, 21% of all the prescriptions filled by Dave's were for controlled substances. GE-24, at 23; Tr. 368. In addition, the number of dosage units of oxycodone and hydrocodone that Dave's dispensed were both higher than the national average. GE-24, at 24.

160. In June 2017, 19% of all controlled substance prescriptions filled by Dave's were paid for in cash. GE-24, at 23; Tr. 368.

161. In June 2017, Dave's filled prescriptions from 11 practitioners whose DEA registrations could not be verified. GE-24, at 24, 30; Tr. 368.

162. In June 2017, Dave's dispensed 14 trinity drug cocktails. GE-24, at 24; Tr. 369.

163. A Pro-Compliance Report for Dave's lists identical DEA registration numbers for two different practitioners. GE-24, at 16, 32; Tr. 369-70. The Pro-Compliance Report indicates that the registration number could not be verified for either practitioner. *Id.* It is not possible for different practitioners to have the same DEA registration number. Tr. 370.

164. There is no evidence in the Administrative Record that the Respondent suspended any shipments of controlled substances to Dave's. Tr. 384-85.

Hephzibah Pharmacy

165. A Pro-Compliance Report for Hephzibah indicates that 27% of all the prescriptions filled by Hephzibah in February 2017 were for controlled substances, and of those prescriptions, 41% were for Schedule II drugs. GE-25, at 5; GE-45, at Summary tab; Tr. 370-71. That percentage of controlled substances was higher than the national average. GE-25, at 6. In addition, the number of dosage units of oxycodone and hydrocodone that Hephzibah dispensed were both higher than the national average. GE-25, at 6. The report also encouraged the Respondent to discuss the concerns addressed in the report with Hephzibah "[t]o gain a better understanding of [its] dispensing practices," and that an on-site visit "may also be prudent." *Id.*

166. A Pro-Compliance Report for Hephzibah contains a list of the names of 20 practitioners whose DEA registration numbers could not be verified. GE-25, at 14. The first name on the list is paired with an invalid DEA number, because it does not contain any letters. *Id.* DEA does not issue registration numbers to practitioners that are all numbers. GE-25, at

14; Tr. 371. There are two letters at the beginning of each DEA registration number for practitioners. Tr. 371.

167. In February 2017, 36% of all controlled substance prescriptions filled by Hephzibah were paid for in cash. GE-25, at 5; Tr. 371.

168. In February 2017, Hephzibah dispensed 9 trinity drug cocktails. GE-25, at 5-6; Tr. 371.

169. In an email sent on December 13, 2017, Jacob Dickson informed Diversion Investigator Teri Bass that due to the Respondent's due diligence its account with Hephzibah was closed because Hephzibah wanted to change its business model, which the Respondent did not support. GE-72, at 1; Tr. 372-73, 434-35. The email states that Respondent did not find that Hephzibah "exhibit[ed] suspicious activity or excessive orders." GE-72, at 1. The Respondent's due diligence notes concerning Hephzibah, however, read as follows:

> 3/17/2017 After looking at their reports, we will open with the understanding of the customer that they must work on clearing up issues that Pro Compliance found, high cash, trinity & high quantities on Hydrocodone & Oxycodone. Will re-run in 90 days.
> 3/21/2017 Opened this account with an understanding of our compliance program. After a couple of months, they decided they would rather change wholesalers than cooperate with our compliance program.
> 6/20/2017 Account closed.

GE-14, at 23, 26.

170. There is no evidence in the Administrative Record that the Respondent suspended any shipments of controlled substances to Hephzibah. Tr. 384-85.

The Wellness Pharmacy

171. Government Exhibit 26 contains the Pro-Compliance Reports for Wellness Pharmacy. GE-26; Tr. 373. Included in those reports is a 2013 Initial Risk Evaluation Report. GE-26, at 1-7. That evaluation informed the Respondent that Wellness represented a "***low risk.***" *Id.* at 2 (emphasis in original). It also revealed, however, that between April and June 2013, 67% of all the prescriptions filled by Wellness were for controlled substances, which was significantly higher than the national average, and 68% of those prescriptions were for either oxycodone or hydrocodone—46% of the total prescriptions. GE-26, at 2, 7. Government Exhibit 26 also contains four additional Pro-Compliance Reports concerning March 2015; April 2016; November 2016; and October 2017. GE-

26, at 10-12, 14, 21. Those reports show that the percentage of controlled substances that Wellness dispensed for each month was: 68%; 69%; 66%; and 64%, respectively. *Id.* Further, the number of dosage units of oxycodone and hydrocodone that Wellness dispensed in October 2017 were both higher than the national average. GE-26, at 15. In addition, in October 2017, 91% of the controlled substances that Wellness dispensed were Schedule II drugs. GE-26, at 21. Finally, the Respondent was advised to discuss the concerns raised by the October 2017 report with Wellness and that an on-site visit "may also be prudent." GE-26, at 15.

172. A Market Basket Report for Wellness indicates that 84% of all the prescriptions filled by Wellness in January 2016 were for controlled substances. GE-63, at 1; Tr. 374.

173. A Market Basket Report for Wellness indicates that 92% of all the prescriptions filled by Wellness in December 2017 were for controlled substances. GE-63, at 47; Tr. 374.

174. There is no evidence in the Administrative Record that the Respondent suspended any shipments of controlled substances to Wellness. Tr. 384-85.

Wilkinson Family Pharmacy

175. Government Exhibit 27 contains the Pro-Compliance Reports for Wilkinson Pharmacy. GE-27; Tr. 375-76. Included in those reports is an Initial Risk Evaluation Report. GE-27, at 3-16. That evaluation informed the Respondent that Wilkinson represented a "***high risk.***" *Id.* at 4 (emphasis in original). It also revealed that in September 2013, 45% of all the prescriptions filled by Wilkinson were for controlled substances, and 46% of those prescriptions for controlled substances were paid for in cash. *Id.* at 4, 16.

176. A Pro-Compliance Report for Wilkinson indicates that 42% of all the prescriptions filled by Wilkinson in March 2014 were for controlled substances, noting that high quantities of oxycodone and hydrocodone had been dispensed. GE-27, at 20; Tr. 376-77. In addition, 38% of all controlled substance prescriptions filled by Wilkinson were paid for in cash, while only 11% of the non-controlled prescriptions were purchased with cash. *Id.*

177. The March 2014 Pro-Compliance Report revealed that Wilkinson filled prescriptions for "[s]everal prescribers [who] have many incidences of prescribing Trinity combinations to their patients." GE-27, at 20; Tr. 377.

178. In January 2015, 38% of all the prescriptions filled by Wilkinson were for controlled substances, and of those prescriptions, 52% were for Schedule II drugs. GE-27, at 21; Tr. 377-78.

179. In January 2015, 30% of all controlled substance prescriptions filled by Wilkinson were paid for in cash. GE-27, at 21; Tr. 378.

180. Between March 2014 and January 2015, Wilkinson dispensed 26 trinity drug cocktails. GE-27, at 21; Tr. 378.

181. In January 2016, 34% of all the prescriptions filled by Wilkinson were for controlled substances, and of those prescriptions, 54% were for Schedule II drugs. GE-27, at 22; Tr. 378.

182. In January 2016, 27% of all controlled substance prescriptions filled by Wilkinson were paid for in cash. GE-27, at 22; Tr. 379.

183. Between January 2015 and January 2016, Wilkinson dispensed 21 trinity drug cocktails. GE-27, at 22; Tr. 379.

184. In August 2016, 31% of all the prescriptions filled by Wilkinson were for controlled substances, and of those prescriptions, 55% were for Schedule II drugs. GE-27, at 23; Tr. 379.

185. In August 2016, 17% of all controlled substance prescriptions filled by Wilkinson were paid for in cash, while only 9% of all prescriptions were purchased with cash. GE-27, at 23; Tr. 379.

186. Between January 2016 and August 2016, the number of dosage units of oxycodone dispensed by Wilkinson increased 10 percent. GE-27, at 23; Tr. 379. When asked if this increase is a concern, Dunn testified, "It's definitely significant." Tr. 380.

187. Between January 2016 and August 2016, Wilkinson dispensed 20 trinity drug cocktails. GE-27, at 23; Tr. 380.

188. From January 2, 2017 to January 31, 2017, 30% of all the prescriptions filled by Wilkinson were for controlled substances, and of those prescriptions, 55% were for Schedule II drugs. GE-27, at 25-26, 32; Tr. 380. Further, the number of dosage units of oxycodone and hydrocodone that Wilkinson dispensed were both higher than the national average. GE-27, at 26, 32. This report also advised the Respondent to discuss the

concerns raised by the January 2017 report with Wilkinson and that an on-site visit "may also be prudent." GE-27, at 26.

189. A Pro-Compliance Report for Wilkinson indicates that Wilkinson filled prescriptions from January 2, 2017 to January 31, 2017, for 46 practitioners whose DEA registrations could not be verified. GE-27, at 25-26, 32; Tr. 380-81.

190. Between January 2, 2017 to January 31, 2017, Wilkinson dispensed 14 trinity drug cocktails. GE-27, at 26, 32; Tr. 381.

191. There is no evidence in the Administrative Record that the Respondent suspended any shipments of controlled substances to Wilkinson. Tr. 384-85.

The Respondent's Policies & Procedures

192. The Respondent's Standard Operating Procedures Manual ("SOP Manual") is dated August 22, 2016. GE-18, at 1.

193. The SOP Manual says that the details of the Respondent's suspicious order monitoring program "are confidential and therefore are not made a part of this manual." Tr. 306; GE-18, at 17.

194. The SOP Manual says that the Respondent "keeps a system in operation which is designed to discover those purchasing patterns of controlled substances which exceed the norm and could possibly be related to diversion activities." Tr. 307; GE-18, at 19. Dunn testified that the requirements of 21 C.F.R. § 1301.74(b) are "a little more encompassing than just the statement exceed the norm." Tr. 307.

195. The SOP Manual describes three methods for identifying suspicious orders: (1) Controlled Drug Volume Analysis Program; (2) Management Oversight; and (3) Employee Oversight. GE-18, at 19-20.

196. The SOP Manual describes a Controlled Drug Volume Analysis Program that generates a monthly report that is reviewed by management. Tr. 308; GE-18, at 19. Dunn does not recall seeing one of these reports in any of the documents the Respondent produced in response to DEA's subpoenas. Tr. 308. Dunn also does not recall seeing any such report or any reference to such a report in the materials he reviewed concerning the Respondent. Tr. 308-09.

197. The section on Management Oversight states that "[a] daily controlled drug sales report is reviewed by management each day." GE-18, at 20; Tr. 491. In the documents Dunn

reviewed for this case he does not recall seeing any daily controlled drug sales reports. Tr. 491.

198. The SOP Manual states that "[w]hen a suspicious pattern or purchase is identified by any of the above methods the customer is contacted in some but not all cases and asked for a written explanation for the unusual order. In all cases, a letter is sent to the DEA indicating a possible suspicious order. Customer supplied information is included when available." GE-18, at 20; Tr. 311-12, 391. In Dunn's opinion, this does not comply with DEA regulations because the distributor should contact the customer in every case where a suspicious order is identified. Tr. 311-12, 484.

199. Despite the SOP Manual saying that "[i]n all cases, a letter is sent to the DEA indicating a possible suspicious order," DEA only received three suspicious order reports from the Respondent between 2014 and 2018. GE-18, at 20; Tr. 312, 731.

200. Of the three suspicious order reports the Respondent sent to DEA, none of them contained customer-supplied information. Tr. 312-13.

201. The Respondent shipped each of the three orders for which it submitted suspicious order reports. Tr. 294.

202. Based on the SOP Manual, Dunn testified that the Respondent's suspicious order monitoring program did not look for the things required under 21 C.F.R. § 1301.74(b). Tr. 307-08.

203. The Respondent's Policies & Procedures Manual for Prescription Drug Handling ("Policies & Procedures Manual") is dated February 2018. Tr. 313; GE-17.

204. The Policies & Procedures Manual describes its SOM program as "a three-fold approach to monitor all prescription drug and/or device orders, including unusual ordering patterns, amounts, and payments to identify any potential diversion or criminal activity." GE-17, at 12; Tr. 314.

205. The Respondent's three-fold approach includes Pro-Compliance Reports, Market Basket Analysis Reports, and Order Processing and Delivery Personnel. GE-17, at 12.

206. The Policies & Procedures Manual says that Pro-Compliance Reports are run annually or "more frequently as needed at the discretion of the Compliance officer." GE-17, at 12; Tr. 315.

207. Between January 2014 and May 2018, Ms. Guin and Jacob Dickson were responsible for the Respondent's compliance program. Tr. 315, 401-02, 736, 794, 835-36. Ms. Guin's manager was Jacob Dickson. Tr. 794. Ms. Guin was removed as compliance officer in May 2018. Tr. 736.

208. The description of the Market Basket Report in the Policies & Procedures Manual mentions a "normal range" for controlled drug orders. GE-17, at 12; Tr. 315. In the documents the Respondent produced to DEA, Dunn did not see any documents discussing normal ranges for any customer. Tr. 315-16.

209. The description of the Market Basket Report in the Policies & Procedures Manual says that the Compliance officer "may stop shipment on any order if he or she finds the order to be unusually suspicious." GE-17, at 12; Tr. 316. In the documents the Respondent produced to DEA, Dunn did not see any documents indicating that the Compliance officer stopped shipment of any order of controlled substances identified as suspicious.[17] Tr. 315-16.

210. The section of the Policies & Procedures Manual labeled "Order Processing and Delivery Personnel" refers to orders that diverge "from normal operations." GE-17, at 12. In the documents the Respondent produced to DEA, Dunn did not see any documents defining what would be considered "normal operations." Tr. 316.

211. The section of the Policies & Procedures Manual labeled "Order Processing and Delivery Personnel" says that "personnel should watch for the appearance of criminal or suspect activity." GE-17, at 12; Tr. 316-17. In the documents the Respondent produced to DEA, Dunn did not see any documentation of criminal or suspect activity. Tr. 316-17.

212. The section of the Policies & Procedures Manual labeled "Records" says that "[r]ecords of a suspect product investigation resulting in the finding of a suspect product shall be maintained in the Company's records for six (6) years. Records of investigations of illegitimate product must be kept for six (6) years, including a notation of the ultimate

[17] Government Exhibit 14 is a phone log of the Respondent's Compliance officer, Clara Guin. *See* GE-13, at 1, para. 2. In the 33 pages of Government Exhibit 14, covering the period of January 5, 2016 to February 28, 2018, there is only one entry concerning a stopped shipment, that being the first entry of 1/9/2018. GE-14, at 31. There are, however, numerous entries suggestive of suspicious orders. *See, e.g.*, GE-14, at 3, entry of 2/1/2016, and second entry of 2/10/2016; at 4, entry of 3/7/2016; at 7, first entry of 6/10/2016; at 8, last entry of 7/20/2016; at 9, last entry of 8/8/2016; at 23, entry of 2/24/2017, entry of 3/17/2017, and first entry of 3/21/2017; at 24, first entry of 4/20/2017; at 25, second entry of 5/10/2017; at 26, second entry of 7/12/2017; at 27, last entry of 8/3/2017; at 29, second entry of 11/2/2017; at 31, first entry of 12/13/2017, and all three entries of 1/9/2018.

disposition of the product after investigation." GE-17, at 15-16. This section on records does not refer to suspicious order monitoring records or due diligence records. Tr. 317-18.

The Tukey Method of Statistical Analysis

213. Rose applied the Tukey method to perform his analysis of Respondent's oxycodone and hydrocodone transactions. Tr. 199.

214. Rose used the Tukey method because it is "a more flexible method for dealing with" irregular distribution patterns. Tr. 199; *see also* Tr. 522. (Weinstein testifying that Tukey "doesn't assume that [the data is] . . . a normal distribution"). Market data does not follow a normal distribution. Tr. 195, 522.

215. The Tukey method of statistical analysis is a useful tool for identifying outlier transactions that a distributor should investigate. Tr. 225, 236-37. The Tukey method is a widely-recognized and commonly-used method of identifying statistical outliers. Tr. 200, 209, 236-37, 521-22, 654.

216. The four components of the Tukey method are the 25th percentile (first quarter), the 75th percentile (third quarter), the interquartile range ("IQR"), and the IQR multiplier. Tr. 201-03. The IQR is the difference between the first and third quartiles, which is then multiplied by a factor of 1.5-6. Tr. 202. The IQR is applied to the third quartile, or 75th percentile, to identify "approximate indications of . . . unusuality." Tr. 202.

217. There is no single correct IQR multiplier to apply in the Tukey method. Tr. 523. There is no rule requiring the use of an IQR multiplier of 3 ("3 IQR"). Tr. 523. The IQR multiplier should be selected based on the data being examined and what the analyst is looking for. Tr. 523.

218. In general, higher IQR multipliers will identify fewer outliers because the higher multipliers raise the threshold of what is considered an outlier. Tr. 524. A 1.5 IQR produces an outside value and 3 IQR produces a "far out" value. Tr. 523.

219. Applying a lower IQR multiplier, such as 1.5, would produce more outliers than a higher IQR multiplier. Tr. 202-03, 655-56. DEA did not want to be "overly onerous" on registrants so Rose applied a 3 IQR instead of 1.5. Tr. 202-03. Rose used a 3 IQR because he found it to "work[] very well at identifying what are called far out or extreme

outliers." Tr. 203, 233, 242. By using a 3 IQR, Rose calculated a smaller group of outliers than he would have had he used 1.5 IQR. Tr. 203.

220. A transaction that falls outside of 3 IQR above the 75th percentile is an unusually large transaction, which would occur less than 1% of the time. Tr. 238-39.

Rose's Analysis & Opinions

221. Government Exhibit 67 is a copy of Rose's curriculum vitae. Tr. 191.

222. Rose was qualified, without objection, as an expert in "developing and implementing statistical models and methods of analyzing large and complex data sets." Tr. 192.

223. Rose was provided a set of ARCOS data concerning Respondent's oxycodone and hydrocodone sales from January 1, 2014 to September 30, 2018. Tr. 193-94, 217. He later obtained data of Respondent's sales of oxycodone and hydrocodone through April 30, 2019. Tr. 194. ARCOS categorizes data by sales, distributions, transactions, and returns. Tr. 217.

224. Rose analyzed data of Respondent's sales of oxycodone and hydrocodone from January 1, 2014 to April 30, 2018. Tr. 193-94, 198, 217. To conduct his analysis, Rose looked at transactions, which he defined as the number of dosage units of oxycodone and hydrocodone sold to a pharmacy. Tr. 196. Rose's analysis compared every transaction to a pharmacy made from January 1, 2014 to April 30, 2018, against every other transaction made during the same time period to the same pharmacy. Tr. 197-98, 226-27. Rose called this a fixed-frame analysis. Tr. 197.

225. There was no material difference in the outcome between a fixed-frame and a "moving-frame," or "look-back," analysis.[18] Tr. 198-99, 227-28. Both types of analysis "produce the same basic result, which is to identify a body of outliers that . . . would be worthy of further study." Tr. 199.

226. Rose used the easier fixed-frame method because he was looking for "a ballpark estimate of scale, of size of outlier population," not the exact number of outliers. Tr. 227, 234.

227. Rose's initial analysis incorrectly applied the IQR to the median of the data set (the 50th percentile) instead of the 75th percentile. Tr. 208-09. This incorrect analysis produced "a much larger group of outliers." Tr. 209. Once the mistake was identified, Rose

[18] Rose used the term "moving-frame" to describe what Weinstein called a "look-back" analysis. Tr. 198. Throughout the rest of this Recommended Decision, I will use the term "look-back" analysis.

corrected the analysis (the "corrected analysis") and he had his analyst "go back and check every other analysis he had done, and he verified that they all had been done correct." Tr. 209.

228. Government Exhibit 65 contains all the transactions concerning oxycodone shipments that Respondent reported to the DEA between January 1, 2014 and April 30, 2018. Tr. 71-72.

229. Government Exhibit 66 contains all the transactions concerning hydrocodone shipments that Respondent reported to the DEA between January 1, 2014 and April 30, 2018. Tr. 71-72.

230. Government Exhibits 65 and 66 also contain copies of the results of Rose's corrected analysis. Tr. 72, 211-12.

231. Rose's corrected analysis identified the following amounts of Respondent's oxycodone and hydrocodone sales as outliers from January 1, 2014 to April 30, 2018:

Substance	2014	2015	2016	2017	2018[19]	Total
Oxycodone	2,097	1,857	1,546	1,361	391	7,252
Hydrocodone	1,919	1,314	1,006	536	173	4,948

Tr. 212-13; GE-65-66, at Summary tab; GDE, at 10.

232. Rose's corrected analysis identified the following amounts of Respondent's oxycodone and hydrocodone sales as outliers for seven exemplar pharmacies from January 1, 2014 to April 30, 2018:

Pharmacy	Oxycodone	Hydrocodone
Wallace	1	6
Bordelon's	50	2
Folse	58	68
Pharmacy Specialties	10	15
Dave's	103	14
Wellness	119	3
Wilkinson	2	49

Tr. 213-14, 216-17, 243; GDE, at 11.

233. The above tables reflect transaction size and not transaction frequency. Tr. 244.

[19] January 1, 2018 to April 30, 2018. Tr. 212, 226.

234. Rose also conducted a look-back analysis which produced results "consistent with what [he] found using the" fixed-frame method. Tr. 228, 235. In his look-back analysis, Rose looked at "the entire population" and not only the eight exemplar pharmacies in the OSC. Tr. 230.

235. In Rose's view, statistical analysis is "one piece of the analysis that is necessary" to comply with DEA's regulations governing distributors. Tr. 223-24.

236. When asked by Respondent's counsel whether Rose's analysis was "just math, right?", Rose answered, "Yes." Tr. 224.

237. Respondent's counsel asked Rose, "So the math is a piece of it, but then there has to be some context around it. Would you agree with that?", and Rose agreed. Tr. 225.

238. The analysis Rose conducted to identify outlier transactions was solely a mathematical analysis and did not consider the context of the transactions. Tr. 225, 234, 540.

239. In Rose's opinion, Respondent should have been conducting the type of statistical analysis that he did to identify outlier transactions for every order it received. Tr. 240-41.

240. The figures on page 11 of the Outlier Detection Overview in the Government Demonstrative Exhibit include data from 2014. Tr. 241-42; ALJ-63. The figures in Respondent Demonstrative Exhibit 4 do not include data from 2014. Tr. 242-43, 531, 539.

241. Government Exhibits 73 and 74 contain an analysis of the Respondent's controlled substance transactions for the period of January 1, 2014 to April 30, 2018, using the look-back analysis recommended by Weinstein rather than the fixed-frame analysis that the Government initially relied upon. Tr. 1084-90.

242. The look-back analysis for oxycodone transactions revealed 6,816 outlier transactions, a 6% reduction when compared to the fixed-frame analysis of 7,252, which the Government previously found. Tr. 1091; GE-73, at Summary tab.

243. The look-back analysis for hydrocodone transactions revealed 5,222 outlier transactions, a 5.5% increase when compared to the fixed-frame analysis of 4,948, which the Government previously found. Tr. 1092; GE-74, at Summary tab.

Weinstein's Analysis & Opinions

244. Respondent Exhibit 24, pages 15-19, is a copy of Weinstein's curriculum vitae. Tr. 506-07.

245. Weinstein does not believe that Rose's findings, contained on page 11 of the Government Demonstrative Exhibit, accurately reflect the number of orders that the Respondent should have reported to DEA. Tr. 525, 551. In Weinstein's opinion, Rose's analysis fails to reliably identify unusually large or suspicious orders. Tr. 558.

246. In Weinstein's opinion, the deficiencies in Rose's analysis can be attributed to Rose's (1) use of a four-year fixed-frame as opposed to the look-back method; (2) his failure to consider the schedule change of hydrocodone; (3) failure to consider package size and formulation; and (4) use of the line item approach as opposed to a cumulative approach. Tr. 525-28, 541-46, 558.

247. With respect to the first deficiency, Weinstein testified that Rose's fixed-frame analysis looked at "data that wasn't available at the time for any given order." Tr. 525. Weinstein testified that Rose's fixed-frame analysis took into account the entire time period of January 1, 2014 to April 30, 2018, to determine the outlier threshold and then compared all the orders against that threshold. Tr. 526-27. Weinstein understood Rose to testify that the Respondent could not have performed this analysis at the time it received an order in 2014, for example, because data from 2015-18 would not have been available at that time. Tr. 527. Weinstein testified that Rose's fixed-frame analysis is something a distributor could not do. Tr. 527.

248. Weinstein also testified that a fixed-frame analysis "wouldn't have an impact on the results" was it not for some changes in the industry during the relevant time period. Tr. 528.

249. In Weinstein's opinion, the results of Rose's analysis are not reliable even if the problem caused by the fixed-frame method is corrected. Tr. 525, 551.

250. With respect to the second deficiency Weinstein identified in Rose's analysis, Weinstein testified that in late 2014 DEA rescheduled hydrocodone from Schedule III to Schedule II. Tr. 539. Because Schedule II is more restrictive than Schedule III, there were fewer orders for hydrocodone after it was rescheduled. Tr. 539. The fixed-frame method compared orders for hydrocodone in 2014 when it was a Schedule III drug to orders in 2015-18 when it was a Schedule II drug. Tr. 539-40. In Weinstein's view, this means orders placed when hydrocodone was a Schedule III drug were identified as outliers

based on a comparison to orders placed when hydrocodone was a Schedule II drug.[20] Tr. 539-40.

251. With respect to the third deficiency, Weinstein testified that Rose's analysis did not take into account package size or formulation, such as pills or liquid form of the drug. Tr. 553, 557. In Weinstein's opinion, this consideration makes a difference. Tr. 553-54.

252. An effective system for identifying suspicious orders, in Weinstein's opinion, should take a cumulative approach and consider factors such as package size, formulation, and brand name or generic versions of the drug. Tr. 554-57. A system that fails to take these types of factors into account may result in the distributor over-reporting orders that are not unusual and not suspicious. Tr. 556.

253. With respect to the fourth deficiency, Weinstein believes a distributor should look at the cumulative amount of a substance that is ordered and not individual line items. Tr. 546-47. A cumulative approach looks at the total number of units purchased (e.g., 2,000 total units of oxycodone). Tr. 545; RDE-6. A line item approach looks at the individual line items that make up the total number of units purchased. Tr. 545. For example, 2,000 dosage units—the cumulative total—may have been purchased by the pharmacy as five separate orders for 100, 100, 300, 500, and 1,000 units. Tr. 545. The line item approach takes into account each individual transaction (five separate orders for 100, 100, 300, 500, and 1,000 units) whereas the cumulative approach only considers the total amount purchased (2,000 units). Tr. 545. Weinstein, however, did not incorporate this cumulative-based approach in any analysis he did in this case, including the analysis he conducted to produce the results reflected in Respondent Demonstrative Exhibit 4. Tr. 550-51.

254. Weinstein testified that it is not possible to correct Rose's analysis for the problems caused by using a line item approach. Tr. 550, 552.

255. Weinstein testified that Rose's line item approach produced outliers that would not have been identified under the cumulative approach. Tr. 551-52. Weinstein also testified that Rose's line item approach misses outliers. Tr. 552-53.

[20] This concern, even if accurate, would only impact 2014 orders for hydrocodone. According to Weinstein, because Schedule II is more restrictive than Schedule III, the Respondent received fewer orders for hydrocodone after it was rescheduled. Tr. 539.

256. Statistical analysis is an appropriate method for identifying suspicious orders. Tr. 654. The Tukey method is an appropriate method to conduct that analysis. Tr. 654. In Weinstein's opinion, however, statistical analysis alone is insufficient to identify *diversion* of controlled substances because there are contextual elements that cannot be gleaned from a pharmacy's ordering data. Tr. 558-59.

257. Weinstein testified that it is not possible to reliably and accurately identify suspicious orders from past years using a look-back analysis that is based solely on mathematical calculations. Tr. 684-85, 687-88. It is not possible because identifying outliers involves more than "just the math," and must account for other factors that are not easy to replicate retrospectively. Tr. 685-88. It is possible, however, to run past years' data through the current system. Tr. 688. While Weinstein could run old data through the system, and conduct the mathematical calculations, he would not know what information the Respondent had at the time it received an order that explained the order, such as if a new medical center opened near the customer that explained an increase in the customer's purchasing.[21] Tr. 688.

258. Weinstein agrees with Rose's description of how the Tukey method works. Tr. 655.

259. The data Weinstein used to conduct his analysis came from Government Exhibits 65 and 66. Tr. 534.

260. The mathematical calculations in Government Exhibits 65 and 66 are correct. Tr. 658.

261. For Weinstein's analysis, he compared orders against transactions from the previous 12 months. Tr. 528-29. Using this approach where Weinstein looked back "only to the prior year, rather than to the full four years," Weinstein did not identify many of the orders identified in Rose's analysis. Tr. 528-29. Weinstein's analysis showed that over 60% of the orders from the seven exemplar pharmacies[22] in 2017 and 2018 identified as outliers by Rose "would not have been identified if compared only to the prior year." Tr. 529-31, 539. And about 50% of the orders from all customers identified by Rose as outliers would not have been considered outliers if those orders were compared only to the prior year. Tr. 529-30, 568.

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[21] Presumably, Weinstein would not know what the Respondent knew because the Respondent did not document what it knew. GE-9, at 1-2; GE-11, at 2, para. IV.

[22] Wallace, Bordelon's, Folse, Pharmacy Specialties, Dave's, Wellness, and Wilkinson. GDE, at 11.

262. Respondent Demonstrative Exhibit 4 represents the results of Weinstein's analysis. Tr. 531-32.

263. The table below reflects the difference between Weinstein's look-back analysis and Rose's fixed-frame analysis for 2017-18.[23] Tr. 537-38, 550-51, 693; RDE-4. Weinstein does not conclude, however, that the orders he identified should have been reported. Tr. 551.

Pharmacy		**2017-2018 Total**
Bordelon's	Rose	23
	Weinstein	9
Dave's	Rose	24
	Weinstein	24
Folse	Rose	69
	Weinstein	2
Wellness	Rose	27
	Weinstein	8
Pharmacy Specialties	Rose	5
	Weinstein	3
Wilkinson	Rose	1
	Weinstein	1
Wallace	Rose	7
	Weinstein	7

264. Concerning the seven pharmacies, Weinstein's analysis identified 54 orders as outliers from January 1, 2017 to April 30, 2018. Tr. 537-38; RDE-4.

265. Weinstein's analysis does not include 2014 because he did not have data from 2013 to compare it to. Tr. 539.

266. Respondent Exhibits 28 and 29 contain Weinstein's look-back analysis of transactions identified by Rose as outliers from January 1, 2017 to April 30, 2018. Tr. 659-60. Those

[23] Weinstein also conducted a comparison of 2015-16 data. I, however, sustained the Government's objection to exclude that data because the Respondent failed to produce Weinstein's calculations for those years. Tr. 533-36, 690-93.

calculations compared each transaction against data from the previous year. Tr. 659-60. For example, for Weinstein's analysis of an order on January 1, 2017, he looked at all of the data from 2016. Tr. 660.

267. Respondent Exhibits 28 and 29 identify which outliers identified by Rose would still be considered outliers if compared only to the prior year's data. Tr. 664. Those transactions that would still be considered outliers based on Weinstein's look-back analysis are marked with a "Y" in the final column. Tr. 664. Weinstein does not know how many transactions would still be outliers based on a look-back analysis, but agreed with Government counsel that it is "certainly in the hundreds. It may be over a thousand." Tr. 663-64. In fact, by count, Respondent Exhibit 28 identifies 1,356 outliers for oxycodone, and Respondent Exhibit 29 identifies 324 hydrocodone outliers from January 1, 2017, to April 30, 2018. RE-28-29; Tr. 663-64.

268. In concluding that some outliers identified by Rose would still be considered outliers under a look-back approach, Weinstein was not concluding that those transactions are, in fact, outliers—only that they would "still be identified as outliers if compared only to the prior year and not making any other adjustments to address any of the other issues." Tr. 664.

269. Weinstein did not conduct any analysis to flag outliers not identified by Rose. Tr. 660-61. He only "assessed [Rose's] outliers relative to the prior year to see if they would still be flagged." Tr. 661. Weinstein's analysis did not "attempt to identify new outliers." Tr. 662.

270. Weinstein testified: "I haven't put forward an analysis of what should have been reported in this case. I've put forward an analysis of . . . one of the issues with Mr. Rose's analysis and the impact that that has." Tr. 550.

271. Weinstein did not render an opinion concerning how many of the Respondent's orders between 2014 and April 2018 should have been flagged as suspicious. Tr. 665.

272. It would be a red flag if a pharmacy received a substantially higher percentage of cash payments for controlled substances than it did for non-controlled substances. Tr. 681.

The Respondent's Old SOM System

273. The version of ECP that the Respondent operated before May 2018 was not as robust as it is currently. Tr. 737-38, 740. The pre-May 2018 version of ECP allowed for "limited

information," such as "basic customer information, some basic licensing information, a limited space for notes," and links to Pro-Compliance Reports and Market Basket Reports. Tr. 740.

274. Page 1 of Respondent Exhibit 31.001 contains notes taken on a customer that were part of the Respondent's pre-May 2018 ECP system. Tr. 741-43.

275. Page 1 of Respondent Exhibit 31.002 contains notes taken on a customer that were part of the Respondent's pre-May 2018 ECP system. Tr. 743-46.

276. Page 3 of Government Exhibit 19 is a screenshot of ECP as it existed in May 2018. Tr. 738.

277. When the Respondent's pre-May 2018 SOM system flagged an order as suspicious, it sent an email or text message to the compliance officer, Ms. Guin. Tr. 728, 778. If Ms. Guin took no action on that flagged order, the order would be shipped because the system did not have the capability to hold the order. Tr. 728-29. To "hold the order," meant that the order would not be shipped. Tr. 778.

278. In Irelan's opinion, the Respondent's pre-May 2018 SOM system was inconsistent with best practices because it did not hold suspicious orders and it did not give the Respondent the opportunity to resolve red flags before shipping the orders. Tr. 729, 778. It was also inconsistent with best practices because the threshold it used to flag orders was based on whether the order was 10 times larger than a 90-day average. Tr. 729-30; GE-9, at 3.

279. Milione testified that the Respondent's reporting of suspicious orders had been insufficient. Tr. 989.

280. The Respondent's old SOM program reportedly consisted of: know your customer efforts; an electronic customer profile ("ECP"); a market basket system; reports from Pro-Compliance; direct contact with and soliciting of information from customers; and reliance on the Respondent's sales force and those who actually filled orders for controlled substances. Tr. 866-70; GE-9, at 2-3; GE-17, at 12; GE-18, at 19-20.

281. The Respondent reportedly terminated 23 customers in 2014, 12 customers in 2015, and 7 customers in 2016, as a result of its old SOM system. Tr. 1014-15; RE-11, at 14. Because these customers were reportedly terminated as a result of the Respondent's SOM system, the Respondent should have submitted suspicious order reports to the DEA concerning the terminated customers. Tr. 1015-16.

The Respondent's New SOM System

282. After the DEA issued the OSC/ISO to the Respondent, Milione contacted the Respondent. Tr. 877-78. The contact led to the Respondent retaining Guidepost to enhance the Respondent's entire DEA compliance program, specifically its SOM system. Tr. 878-79.

283. Milione has worked as a consultant for the Respondent for a little over a year. Tr. 879, 953. Paul Dickson, Sr., authorized Guidepost to work for the Respondent. Tr. 1011. Between May 8, 2018, and December 31, 2018, Guidepost employees have been at the Respondent's Shreveport offices every day. Tr. 879. Those employees included former DEA employees who were experienced in diversion matters. Tr. 880. Guidepost continues to have employees at the Respondent's facilities. Tr. 881. Guidepost employees are also logged into the Respondent's ECP system, and can confer with the Respondent's compliance employees in real time. Tr. 882.

284. When Milione began working with the Respondent he realized that enhancements needed to be made to the Respondent's SOM system. Tr. 990-91. In developing the Respondent's new SOM system, Milione testified that one of the "big things" that the Respondent needed was the capability to flag orders in real time and to report those orders to DEA. Tr. 991, 993. Milione testified that the Respondent "needed a system that would flag order[s] live time and then report those daily." Tr. 993.

285. After Milione began working for the Respondent as a consultant, the Respondent conducted investigations of prescribers' credentials and/or prescribing practices that did not meet the Respondent's obligations regarding compliance. Tr. 1008. The Respondent ceased doing business with some of the pharmacies that filled prescriptions written by those prescribers, and reported the same to the DEA. Tr. 1008-09.

286. Guidepost undertook seven corrective measures on the Respondent's behalf. Tr. 882. Those measures included: (1) establishing an anti-diversion compliance regulatory affairs team; (2) enhancing the Respondent's SOM system; (3) redeveloping the Respondent's ECP; (4) enhancing the Respondent's "know your customer protocols"; (5) enhancing the Respondent's due diligence investigative protocols; (6) conducting employee training; and (7) documenting everything and reporting to DEA. Tr. 882-900.

287. The Analysis Group, Inc., ("AGI") was also brought in to develop a "live real-time order monitoring system that would identify flagged orders for investigation, for canceling, for reporting to DEA." Tr. 885.

288. The Respondent paid Guidepost almost $3,000,000 between the time the OSC/ISO was issued and May 2019 to get into compliance with DEA regulations. Tr. 973-74, 992. Milione testified that the Respondent has "spared no expense" in becoming compliant with DEA regulations. Tr. 992.

289. Weinstein and AGI looked at DEA regulations on suspicious order monitoring, specifically 21 C.F.R. § 1301.74(b), and DEA guidance letters in designing the Respondent's new SOM system. Tr. 626, 630, 634.

290. Weinstein used the Tukey method in developing the Respondent's new SOM system. Tr. 655.

291. AGI began its work with the Respondent in May 2018 by developing "interim thresholds based on an enhanced statistical approach to evaluating Morris & Dickson's orders." Tr. 561. This involved establishing and implementing "item group thresholds for each customer by month." Tr. 561. Weinstein applied these interim thresholds to retail pharmacies and alternate care customers. Tr. 569. Weinstein described an alternate care customer as a pharmacy that exclusively serves a particular facility or patient population and is not open to the general public to fill prescriptions on a walk-in basis. Tr. 570. The Respondent implemented the interim thresholds in May-June 2018 and kept them in place until October 2018 for retail pharmacies and January 2019 for alternate care customers. Tr. 570-71, 577. The Respondent began operating an interim, automated SOM program within a few weeks of retaining AGI. Tr. 577-78. The Respondent implemented a permanent system for retail pharmacies on October 1, 2018, and a permanent system for alternate care customers on January 1, 2019. Tr. 579-80. Weinstein testified that comparing data from a retail pharmacy against an alternate care pharmacy is like comparing apples to oranges because they operate under different business models. Tr. 580, 639. In Weinstein's view, it is important to compare a pharmacy's orders to other pharmacies within the same peer group. Tr. 580-81.

292. The Respondent's current SOM system flags orders that exceed one of several thresholds. Tr. 668. Each customer's threshold is recalculated each month based on recent ordering patterns. Tr. 625, 638, 644-45, 668.

293. Under the Respondent's current system and policies in place since May 2018, all flagged orders are reported to DEA. Tr. 776-77.

294. The suspicious order reports concern orders the Respondent flagged the previous day. Tr. 779-80. They are attached to emails as Excel files. *Id.*

295. All the documents in Respondent Exhibits 20.001 to 20.115 are daily emails submitting suspicious order reports to the DEA. Tr. 781-83. The first email is dated May 14, 2018 (RE-20.001) and the last email is dated July 29, 2018 (RE-20.114).

296. Since May 14, 2018, the Respondent has sent suspicious order reports to DEA on a daily basis. Tr. 889. Since that time, the Respondent has stopped shipping to 12 or 13 customers. RE-20; Tr. 898, 890.

297. Between May 14, 2018 and July 29, 2018, the Respondent submitted 58 suspicious order reports to the DEA. RE-20. In those 58 reports, the Respondent informed the DEA of about 3,915 suspicious orders. *Id.* Applying the Respondent's new SOM program to its orders from early 2018 identified a similar number of suspicious orders.[24] Tr. 666.

298. The Respondent is currently identifying hundreds of flagged orders per month. Tr. 676, 682-83. This number is roughly consistent with the numbers that AGI obtained when it applied its system to the Respondent's sales data prior to AGI implementing its system for the Respondent. Tr. 666, 676, 682-83.

299. Once the customer's threshold for the month is reached, the Respondent's current SOM system holds that customer's orders as potentially suspicious and prevents them from being shipped. Tr. 668-69. If the customer places new orders the next month, the Respondent will ship those orders if all red flags and potential suspicion have been resolved. Tr. 669-70.

300. Under the Respondent's current SOM system, if a customer exceeds the threshold for one item group, the customer is still allowed to order controlled substances from the other

[24] Respondent Exhibit 20 demonstrates that between May 14, 2018 and July 29, 2018, the Respondent notified DEA of 3,915 suspicious orders. In addition, had the Respondent been applying its current SOM system to the orders the Respondent received in early 2018, the SOM system would have identified similar numbers of suspicious orders. Tr. 666. The Respondent, however, did not conduct any calculations to determine whether its new SOM system identified any suspicious orders in the Respondent's sales data before 2018. Tr. 682, 686.

item groups unless the Respondent places a hold on those other item groups as well. Tr. 670-72, 679-80.

301. The Respondent's SOM program that Weinstein and AGI developed performs three core assessments: a monthly assessment based on the customer's ordering history; a monthly assessment comparing the customer to its peer group; and a daily assessment of "the highest priority item groups." Tr. 619, 771. Other components of the system include peer and item group definitions. Tr. 619. The item groups are classified "into different levels of diversion risk that help determine exactly what statistical parameters are applied to each" item group. Tr. 619. The item groups are divided into four categories of risk: priority (highest risk); high-risk subset consisting of oxycodone 30 mg; high risk; and other. Tr. 620-21. These risk classifications and their corresponding Tukey multipliers are depicted on Respondent Demonstrative Exhibit 9. Tr. 621-22.

302. Respondent Demonstrative Exhibit 8 depicts how the peer group, own history, and daily assessments work in the Respondent's SOM system. Tr. 632-37.

303. When the SOM system identifies an outlier, the order is held for further review. Tr. 582, 625, 629, 672, 770, 1017-18. AGI has recommended to the Respondent the types of information it should consider when reviewing an outlier. Tr. 582.

304. Weinstein ran sales data from early 2018 through the new SOM system and the system identified a similar number of outliers to the amount being identified currently. Tr. 666, 676.

305. The Respondent's SOM system is currently flagging "hundreds" of orders of controlled substances per month for exceeding thresholds. Tr. 676-77, 682-83. When asked by Government counsel if it was multiple hundreds per month, Weinstein answered "Yes." Tr. 683. This amount is roughly consistent with the results Weinstein produced when he ran data from early 2018 through the Respondent's current SOM system. Tr. 676-77, 683.

306. If the Respondent ran its current SOM system on past years' data, the system would identify some outliers as suspicious. Tr. 685-86.

The Respondent's Current ECP System

307. The Respondent currently documents its due diligence of suspicious orders in the Enhanced Customer Profile ("ECP"). Tr. 716, 737. The ECP is a "one-stop electronic

dashboard for all customer due diligence" that presents information in an "instantly retrievable" format. Tr. 737. The Respondent operated a version of ECP before May 2018, but it was not as robust as it is currently. Tr. 737-38, 740.

308. The Respondent's current ECP system has two places for notes whereas the pre-May 2018 ECP system had only one place for notes. Tr. 760-61.

309. The Respondent no longer uses Market Basket Reports but continues to use Pro-Compliance Reports. Tr. 716.

310. When an order is flagged as suspicious, it is held for review. Tr. 770, 1017. The ECP system alerts the Respondent's compliance team of the flagged order and a team member is assigned to investigate it. Tr. 770, 778, 1017-18. The Respondent's policy is to presume the order should be cancelled. Tr. 770. In general, under the Respondent's current system and policies in place since May 2018, the majority of flagged orders are cancelled but the order may be shipped if the investigation reveals information justifying the order. Tr. 770-71, 776, 1017-18. Notes taken during investigation of a flagged order are stored in the system and are visible at a glance on a customer's ECP home screen. Tr. 774; RE-23A, at 1. The Respondent looks at ECP data when an order is flagged. Tr. 641-42.

311. Under the Respondent's current procedures, a flagged order for controlled substances will not be "released unless the Guidepost team blesses the release, reviews the justification and what's in the ECP." Tr. 886.

312. Respondent Exhibit 23A contains screenshots of the Respondent's current ECP system. Tr. 753. The amount of information and level of analysis presented in Respondent Exhibit 23A represent the Respondent's current ECP system, and did not exist on the old system displayed on page 3 of Government Exhibit 19. Tr. 738, 753.

313. Page 1 of Respondent Exhibit 23A is the home screen of a customer's ECP profile. Tr. 747. The home screen is divided into five sections. RE-23A, at 1; Tr. 747. The first section includes the customer's contact and licensing information, and the date of the customer's last Pro-Compliance Report. Tr. 747-48. The third section contains flagged order notes. Tr. 774. The home screen also displays information about flagged orders at the top of the page. Tr. 772.

314. Page 5 of Respondent Exhibit 23A is the first page of a site visit report. Tr. 757. Site visits are conducted "for a variety of reasons," including on-boarding a new customer or investigating red flags. Tr. 757.

315. Page 6 of Respondent Exhibit 23A displays two pages of an enhanced due diligence report. Tr. 758. An enhanced due diligence report is a report concerning a customer created by a member of the Respondent's compliance team that does not involve visiting the customer's physical location. Tr. 757-58. This is a full report that includes a customer's contact information, population, demographics, licensing information, employees, top prescribers, background searches, and board actions. Tr. 758.

316. Page 8 of Respondent Exhibit 23A is a snapshot of a customer's on-boarding questionnaire. Tr. 759-60. When the Respondent on-boards a new customer, the customer completes a questionnaire and submits some compliance documents, and a member of Respondent's staff prepares an enhanced due diligence report of that customer and has several phone conversations with the customer. Tr. 759-60.

317. Page 9 of Respondent Exhibit 23A displays purchasing history and threshold amounts. Tr. 751-52.

318. Page 30 of Respondent Exhibit 23A is a prescriber page that allows the Respondent to access information about individual prescribers. Tr. 763.

319. Page 31 of Respondent Exhibit 23A shows information about a specific prescriber. Tr. 764.

320. Page 32 of Respondent Exhibit 23A shows a note on a customer put in by a member of Respondent's compliance team. Tr. 764-65.

321. Page 38 of Respondent Exhibit 23A shows a list of flagged orders, the reason the order was flagged, the status of that flagged order, and the compliance team member who is responsible for investigating that order. Tr. 772-73.

322. Currently, the Respondent verifies the licenses of the pharmacies that place orders with the Respondent. Tr. 958. In addition, the Respondent checks, at minimum, the registrations of a pharmacy's top prescribers. Tr. 960.

323. The Respondent's current ECP system allows the Respondent to conduct due diligence and to keep all the information in a readily retrievable format. Tr. 765.

324. The ECP profile contains a section where key information from Pro-Compliance Reports is displayed "so it's quickly viewable." Tr. 749-50.

325. Pro-Compliance Reports and other pertinent documents, such as site visit reports and enhanced due diligence reports, are accessible through the customer's ECP profile. Tr. 748-49, 756.

326. The Respondent has conducted about 230 customer site visits since the OSC/ISO was issued. Tr. 888.

327. The Respondent sometimes conducts its own analysis of dispensing data. Tr. 756. The Respondent will store the results of that analysis in the ECP system. Tr. 756.

328. If the Respondent's compliance team sees that a customer is dispensing a high volume of trinity prescriptions, the team will conduct additional due diligence. Tr. 750.

329. The Respondent's current ECP system has the capability to verify a customer's DEA registration. Tr. 753-54. The status of the customer's DEA registration is updated every day around the same time. Tr. 754. The ECP system also displays a customer's state license information. Tr. 755.

330. If a member of Respondent's compliance team sees that a customer has a large number of patients who travel long distances to fill prescriptions, the compliance team would conduct enhanced due diligence. Tr. 761.

August 2016 Meeting

331. Milione was the Assistant Administrator of Diversion Control at DEA for two years, and before that he was a DEA Special Agent for about 21 years. Tr. 845-46. Milione retired from the DEA on June 24, 2017. Tr. 940-41. Milione currently works for Guidepost Solutions, which was hired in early May 2018 to enhance the Respondent's SOM system, due diligence, and customer protocols. Tr. 844, 985.

332. Milione regularly met with registrants while he was the Assistant Administrator. Tr. 941.

333. Milione first met Paul Dickson, Sr., in June 2016 at a meeting of the Health Distribution Management Association Board of Directors. Tr. 852.

334. Subsequently, Paul Dickson, Sr., invited Milione to come to Shreveport, Louisiana, to see the Respondent's facility there. Tr. 853. Respondent Exhibit 21 is a copy of the email Milione received inviting him to visit the Respondent. Tr. 854.

335. Milione met with the Respondent at its facilities in Shreveport on August 17, 2016. Tr. 856-57, 941. Several other DEA employees attended the meeting, to include Diversion Investigator Bass. Tr. 857, 859. The Respondent's representatives at the August 2016 meeting included Paul Dickson, Jacob Dickson, Clara Guin, and Eric Mutter, who worked for Pro-Compliance. Tr. 859.

336. The August 2016 meeting lasted one-and-a-half to two hours. Tr. 860, 976. The Respondent's SOM system was discussed at the meeting. Tr. 861, 976, 1107.

337. Respondent Exhibit 11 is a Power Point presentation concerning the Respondent's SOM system that the Respondent presented to Milione at the August 2016 meeting.[25] Tr. 864-65, 1013-14.

338. The Power Point presentation indicates that utilizing its old SOM system the Respondent had cancelled the accounts of 42 pharmacies between 2014 and 2016. Tr. 1014-16; RE-11, at 14.

The Respondent's Acceptance of Responsibility

339. In May 2018, Irelan unofficially became the Respondent's Director of Corporate Compliance and Security. Tr. 699, 791. It was unofficial because the Respondent did not have a corporate title for Director of Compliance until officially creating that title in June or July 2018. Tr. 699, 791. Irelan's objective as Director of Corporate Compliance is to ensure the Respondent has effective controls in place to prevent diversion. Tr. 700. Mr. Dickson offered him the position. Tr. 699-700.

340. Paul Dickson, Sr. removed himself from oversight of the Respondent's compliance program around May 2018. Tr. 784. Since that time, Irelan has had limited interaction with Paul Dickson, Sr. Tr. 783-84.

341. Irelan had no involvement in or responsibility for the Respondent's SOM system from January 2014 to May 2018. Tr. 723. Irelan also had no involvement in or responsibility for reporting suspicious orders before May 2018. Tr. 731-32.

342. Irelan was also not involved in the Respondent's due diligence before May 2018, but he "understood basic concepts of due diligence" to the extent it involved delivery drivers

[25] Although the cover of Respondent Exhibit 11 bears the date "August 17, 2017," Milione testified that the presentation was in 2016. Tr. 864.

observing suspicious activity at stores. Tr. 710, 793. Irelan had no idea what a red flag was before May 2018. Tr. 793.

343. Irelan does not have any ownership interest in the Respondent, which is owned by the Dickson family. Tr. 694, 836.

344. Irelan testified that he has the authority to bind the Respondent in contractual agreements regarding certain matters, such as the purchase of equipment. Tr. 837-38.

345. Irelan has never signed an agreement settling a lawsuit against the Respondent. Tr. 839.

346. Irelan is not required to obtain approval from anyone regarding the Respondent's budget for its compliance team. Tr. 784.

347. No member of Paul Dickson, Sr.'s family has complained to Irelan about the expense of operating the Respondent's compliance team. Tr. 785.

348. Irelan is not required to discuss with any member of the Respondent's management about decisions he makes regarding suspicious order monitoring. Tr. 785.

349. No one at the Respondent has suggested to Irelan that he cannot take actions that he wants to take regarding compliance. Tr. 784.

350. No one has ever told Irelan he cannot hire or terminate a member of the Respondent's compliance team. Tr. 785. Irelan is the final decision maker regarding staffing the Respondent's compliance team. Tr. 785.

351. The Respondent's sales personnel have no influence on the compliance team's decision to cancel an order, to report an order to DEA, to reject a potential new customer, or to terminate a customer for compliance issues. Tr. 785-86.

352. The Respondent's compliance team works with AGI, Guidepost, and the law firm Cadwalader, and Irelan does not have any plans on ending the Respondent's working relationship with those firms. Tr. 801.

353. Irelan would not feel comfortable terminating the Respondent's employment of Guidepost or AGI without first taking that decision to the company's Board. Tr. 803-04, 837. The Board, however, could terminate the Respondent's employment of Guidepost or AGI without receiving input from Irelan. Tr. 840.

354. Paul Dickson, Sr. could fire Irelan, Guidepost, AGI, or Cadwalader. Tr. 804-05.

355. In Irelan's opinion, Ms. Guin and Jacob Dickson are to blame for the Respondent's compliance failures for which Irelan accepts responsibility. Tr. 807-09.

356. Irelan testified that based on his review of the Respondent's records, before May 2018 the Respondent conducted "a tremendous amount of due diligence" of its customers. Tr. 704-05, 710. Irelan testified, however, that the Respondent did not keep the due diligence documentation "in such a way as to make it . . . easily accessible." Tr. 705, 710, 720; *see, e.g.*, GE-9, at 2; GE-11, at 1, para. 3; GE-11, at 2, para. 4.

357. Based on his experience as Director of Corporate Compliance, Irelan believes the Respondent's due diligence practices before May 2018 were insufficient, primarily because the due diligence documentation was "not properly maintained to be . . . easily retrievable." Tr. 705, 720. Irelan also testified that although the Respondent conducted due diligence, that information was not applied at the order level. Tr. 720-21.

358. Irelan testified that he accepts responsibility on the Respondent's behalf for the Respondent's SOM system during January 2014 to May 2018 as being inconsistent with best practices. Tr. 730-31. He also testified that he accepts responsibility on the Respondent's behalf for preventing reoccurrence of the failures of Respondent's old SOM system. Tr. 731.

359. Irelan testified that he accepts responsibility on the Respondent's behalf "for preventing reoccurrence of the company's past failures with respect to application of customer due diligence." Tr. 721-22.

360. Irelan testified that he accepts responsibility on the Respondent's behalf "for the company's failures for the period between January 2014 and May 2018 to effectively apply its customer due diligence in assessing orders of controlled substances." Tr. 722-23.

361. Irelan testified that he accepts responsibility for the Respondent shipping orders of controlled substances from January 2014 to May 2018 without conducting due diligence of those orders. Tr. 806-07.

362. Irelan testified that he accepts responsibility on the Respondent's behalf for the Respondent's failure to report suspicious orders from January 2014 to May 2018. Tr. 732-33. Irelan also testified that he accepts responsibility on the Respondent's behalf for correcting the Respondent's failure to report suspicious orders and for preventing the reoccurrence of the Respondent's failure to report suspicious orders. Tr. 732.

363. Irelan testified that he accepts responsibility for the Respondent shipping orders of controlled substances from January 2014 to May 2018 without resolving red flags of those orders. Tr. 807.

364. Irelan testified that he accepts responsibility for the Respondent having a non-functioning compliance system from January 2014 to May 2018. Tr. 807.

365. Irelan testified that the Respondent accepts responsibility for the allegations in paragraphs 10, 17, 21, 23, 39, 47, 48, 51, 52, 66, and 73 of the OSC. Tr. 813, 816-18, 827-28, 830-31; ALJ-1, at 3, 5, 6, 8, 9, 11, 12.

366. Irelan testified that the Respondent does not accept responsibility for the allegations in paragraphs 22 and 35 of the OSC. Tr. 817, 825; ALJ-1, at 6-7.

367. Irelan testified that the Respondent does not accept responsibility for the allegations in paragraph 32 of the OSC except it does accept responsibility for the part about failing to report potentially suspicious orders. Tr. 824-25; ALJ-1, at 7.

368. Irelan testified that he is not in a position to say whether the Respondent accepts responsibility for the allegations in paragraphs 24, 29, and 82 of the OSC. Tr. 821-23, 831-33; ALJ-1, at 6-7, 10, 13.

369. With respect to the allegations in paragraph 63 of the OSC, Irelan testified that he could not speak on additional due diligence that was or was not conducted because of the Respondent's poor record keeping at the time. Tr. 829-30; ALJ-1, at 11.

370. With respect to the allegations in paragraph 91 of the OSC, Irelan testified that the Respondent conducted additional due diligence but it was not properly applied. Tr. 832-33; ALJ-1, at 14.

371. With respect to the allegations in paragraph 58 of the OSC, Irelan accepted responsibility except that he testified that the Respondent did conduct additional due diligence and that at some point the Respondent cut off Pharmacy Specialties, but he did not know when that occurred. Tr. 828-29.

372. When asked by Government counsel how the Respondent can ensure that its past failure to report suspicious orders is not repeated, Irelan pointed to "the enhancement of ECP" and daily suspicious order reports that are emailed to Dunn and reviewed by the Respondent's compliance team every day. Tr. 777-78.

ANALYSIS

The Order to Show Cause afforded the Respondent the opportunity to demonstrate why its Certificate of Registrations should not be revoked pursuant to 21 U.S.C. § 824(a)(4). Under that portion of the United States Code, a distributor's registration may be suspended or revoked upon a finding that the distributor "has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section . . . ." With regard to distributors of schedule II controlled substances Congress has set forth five factors to consider when determining whether the distributor's registration would be in the public interest. The factors to be considered are:

> (1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
> (2) compliance with applicable State and local law;
> (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
> (4) past experience in the distribution of controlled substances; and
> (5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. § 823(b).

The DEA considers these public interest factors separately. *Ajay S. Ahuja, M.D.*, 84 Fed Reg. 5479, 5488 (2019); *Masters Pharm., Inc.*, 80 Fed. Reg. 55418, 55472 (2015), *pet. for rev. denied*, 861 F.3d 206 (D.C. Cir. 2017); *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 Fed. Reg. 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Masters Pharm.*, 80 Fed. Reg. at 55473. Furthermore, there is no requirement to consider a factor in any given level of detail. *Trawick v. DEA*, 861 F.2d 72, 76-77 (4th Cir. 1988). When deciding whether registration is in the public interest, the DEA must consider the totality of the circumstances. *See generally Joseph Gaudio, M.D.*, 74 Fed. Reg. 10083, 10094-95 (2009) (basing sanction on all evidence of record).

With respect to Factor One, concerning the maintenance of effective control against diversion, the DEA has promulgated regulations to guide the regulated community. Specifically,

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74(b). In addition, while the DEA regulations do not explicitly require a distributor to maintain records that document its efforts to maintain effective controls against diversion, "documenting . . . is still an essential part of maintaining effective controls against diversion." *Masters Pharm.*, 80 Fed. Reg. at 55428 n.21. Further, the requirement to report suspicious orders "exists to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." *Southwood Pharm., Inc.*, 72 Fed. Reg. 36487, 36501 (2007).

As with all enforcement actions the DEA brings against a registrant, the Government bears the initial burden of proof, and must justify revocation by a preponderance of the evidence. *Steadman v. SEC*, 450 U.S. 91, 100-03 (1981); *Masters Pharm.*, 80 Fed. Reg. at 55473; 21 C.F.R. § 1301.44(e). If the Government makes a *prima facie* case for revocation, the burden of proof shifts to the registrant to show that revocation would not be inconsistent with the public interest. *Masters Pharm.*, 80 Fed. Reg. at 55473; *Med. Shoppe—Jonesborough*, 73 Fed. Reg. 364, 387 (2008); *Gregory D. Owens, D.D.S.*, 67 Fed. Reg. 50461, 50464 (2002). A registrant may prevail by successfully attacking the veracity of the Government's allegations or evidence. Alternatively, a registrant may rebut the Government's *prima facie* case for revocation by accepting responsibility for wrongful behavior and by taking remedial measures to "prevent the re-occurrence of similar acts." *Jeri Hassman, M.D.*, 75 Fed. Reg. 8194, 8236 (2010) (citations omitted). In addition, when assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of the offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, M.D.*, 78 Fed. Reg. 38363, 38385 (2013).

I. The Government's Position

The Government presented its position in an opening statement, Tr. 25-30, and in its Post-Hearing Brief ("Government Brief"), submitted on August 2, 2019.[26] I have read and considered the Government's opening statement, and its post-hearing brief, in preparing this

[26] The Government's Brief has been marked as ALJ-90.

Recommended Decision.

In its Brief, the Government's proposed findings of fact are essentially the same as the findings of fact set forth in this Recommended Decision. ALJ-90, at Appendix ("App.") A. To the extent the Findings of Fact in this Recommended Decision differ from those proposed by the Government, it is because I have found the Government's proposed findings to be in error or not relevant to resolve the issues in this case. I specifically reject some of the Government's proposed findings of fact.[27] The Government also utilizes 21 U.S.C. § 824(a) as a procedural framework. ALJ-90, at 27. While listing the five public interest factors of 21 U.S.C. § 823(b), the Government specifically notes that it does not rely on Factors Three or Five, and it makes no argument concerning Factor Two. *Id.* at 27-29 & n.12. The Government combines its analysis of Factors One and Four. *Id.* at 28-44. In addition, the Government clearly set forth its allegations concerning the Respondent. *Id.* at 6-12.

In its Brief, the Government argues that under the Controlled Substances Act, and its enacting regulations, the Respondent has numerous obligations. ALJ-90, at 13. Of those obligations, two are the most relevant in this case. First, a distributor must maintain effective controls against diversion of controlled substances, and second, a distributor must design and operate a system that can identify suspicious orders of controlled substances, so as to allow the distributor the ability to report those suspicious orders to the DEA. *Id.* These obligations create two related and partially overlapping obligations for the distributor: a due diligence requirement; and a reporting requirement. *Id.* at 14. These obligations are well-established and have been the subject of DEA decisions, written guidance, and presentations. *Id.* Citing *Masters Pharm., Inc.*, 80 Fed. Reg. at 55480 n.166, the Government notes that a registrant is charged with the knowledge of its regulatory responsibilities. ALJ-90, at 14. The Government argues that, based on the guidance from DEA, it has been clear for at least a decade that distributors cannot ship

[27] The Government's proposed findings of fact include the specific number of dosages of controlled substances the Respondent shipped to specific exemplar pharmacies. ALJ-90, App. A, paras. 96, 97, 108, 109, 130, 131, 145, 146, 170, 171, 179, 180, 203, 204, 227, 228. I reject those proposed findings for several reasons. First, the numbers of shipped dosages to the pharmacies that the Government now alleges in its Brief were not disclosed in the Order to Show Cause or in prehearing filings. Second, there is no testimony concerning the number of dosage units shipped to the pharmacies. Third, the Government's summary of evidence contained on its CD-ROMs does not detail the number of dosage units shipped to the pharmacies. ALJ-64, at 31-32. Lastly, while the total number of dosages may be documented in Government Exhibits 65 and 66, neither I, nor the Administrator, are obligated to break out a calculator and add up thousands of line entries contained in an Excel spreadsheet to confirm the accuracy of the Government's calculations. Suffice it to say, these exhibits show that the Respondent shipped thousands of orders of oxycodone and hydrocodone containing thousands of dosage units to the exemplar pharmacies. And the Respondent has not rebutted that evidence.

orders of controlled substances without conducting due diligence and that they must report suspicious orders to the DEA. *Id.* at 15.

Customer-based Due Diligence

Quoting from *Holloway Distributing*, 72 Fed. Reg. 42118, 42124 (2007), the Government notes that "a registrant has an affirmative duty to protect against diversion by knowing its customers and the nature of [their controlled substances] sales." ALJ-90, at 15 (alteration in original). Relying on *Masters Pharm., Inc.*, 80 Fed. Reg. at 55477, the Government also argues that a distributor's duty to perform due diligence concerning its customers is based on the requirement that a registrant provide effective controls and procedures to guard against theft and diversion of controlled substances. ALJ-90, at 15; *see also* 21 C.F.R. § 1301.71(a). To satisfy the due diligence requirement, a distributor should look for any information that raises a serious doubt as to the legality of the business practices of one of its customers. ALJ-90, at 15. In doing so, a distributor should realize that the threshold for suspicion is low. *Id.* at 16. To help distributors, the DEA issued a letter to distributors in 2006, which identified areas of concern for a distributor to evaluate. *Id.* DEA decisions have also identified areas of concern of which a distributor should be cognizant. *Id.* at 17. Examples of those concerns include: dispensing trinity drug cocktails; the ratio of controlled to non-controlled prescriptions dispensed by a pharmacy; and the percentage of prescriptions that are paid for in cash at a pharmacy. *Id.*

Citing *Holloway Distributing*, 72 Fed. Reg. at 42124, the Government argues that a distributor has an affirmative duty to seek out such information. ALJ-90, at 17. The distributor must conduct an investigation into these concerns before it ships an order to a customer. *Id.* at 18. Furthermore, "a registrant cannot claim that it has conducted meaningful due diligence or has an effective suspicious orders monitoring program when it ignores information it has acquired which raises a substantial question as to the legitimacy of a customer's dispensing practices." *Id.* at 18 (quoting *Masters Pharm., Inc.*, 80 Fed. Reg. at 55478). Accordingly, the Government argues that, "[a] distributor who fails to dispel ***all*** indicia of suspiciousness about a customer's business practices ***prior to shipment*** of any controlled substances—or who fails to properly document the performance of this investigation—has failed to maintain effective controls against diversion and, thus, violates the CSA and the regulations." *Id.* at 18-19 (emphasis in original).

Monitoring Orders and Reporting Requirements

The Government argues that in addition to the obligation to conduct due diligence on its customers, a distributor must also review every order it receives and identify suspicious transactions before filling those orders. ALJ-90, at 19. In fact, the distributor has an affirmative duty to not fill an order until it determines that the order is legitimate. *Id.* (citing *Novelty Distribs., Inc.*, 73 Fed. Reg. 52689, 52699 (2008)). Thus, a distributor must: develop and implement a system to identify suspicious orders; conduct adequate due diligence to dispel concerns before shipping such an order; and report orders to the DEA where the indicia of suspiciousness could not be resolved. ALJ-90, at 19. Again, the Government notes that the threshold for suspiciousness is a fairly low standard. *Id.* at 20.

The Government also notes that suspicious orders are not limited to orders of unusual size, pattern, or frequency. ALJ-90, at 21. Information that raises concerns while conducting due diligence of a customer also might make an order suspicious even though the order is not of unusual size, pattern, or frequency. *Id.* at 22 (citing *Masters Pharm., Inc.*, 80 Fed. Reg. at 55478).

In the Government's view, under 21 C.F.R. § 1301.74(b) a distributor has two options once it has identified a suspicious order. ALJ-90, at 22. The distributor can report the order to the DEA and decline to fill the order, or the distributor can conduct an investigation which dispels all indicia of suspiciousness and then fill the order. *Id.* at 22-23. The Government recognizes some conflict in its position with the testimony of several witnesses.[28] *Id.* at 22-23 n.8. There is language in *Masters Pharm., Inc.*, that indicates that a distributor has an obligation to report an order as suspicious once the distributor had "flagged" the order by use of its SOM system. *Id.* In essence, an order is perceptibly suspicious once it has been flagged. *Id.* When a

[28] The Government also states that I need not resolve this conflict. ALJ-90, at 22-23 n.8. I agree with the Government that there is tension in the *Masters* Final Order about when a distributor is required to report suspicious orders and whether the distributor can be exempted from that requirement by resolving the suspicion. ALJ-90, at 22-23 n.8 (quoting *Masters Pharm., Inc.*, 80 Fed. Reg. at 55478). Any language in *Masters* that suggests that a distributor can be exempted from reporting suspicious orders conflicts with the clear, unambiguous directive in the regulation to report suspicious orders "when discovered," not after an investigation fails to resolve the suspicion. 21 C.F.R. § 1301.74(b); 80 Fed. Reg. at 55478 & 55479 n.164. Furthermore, it even conflicts with other language in *Masters* that says that once an order arouses, or should arouse, suspicion and is held for review, that order meets the low standard for being suspicious and must be reported pursuant to 21 C.F.R. § 1301.74(b). 80 Fed. Reg. at 55487 n.178. I also agree with the Government that "[w]hatever Section 1301.74(b) requires, Respondent failed to do it." ALJ-90, at 22-23 n.8. Accordingly, I will follow the testimony of the witnesses, and the language of *Masters* that once an order has been placed on hold it already meets the criteria of being suspicious and must be reported. 80 Fed. Reg. at 55487 n.178.

distributor has obtained information that an order is suspicious but chooses to ignore that information and fails to report the order, the distributor has violated 21 C.F.R. § 1301.74(b). *Id.* at 23-24.

Duty to Investigate Before Shipping

Even if a distributor reports an order as suspicious to the DEA, the distributor still must conduct due diligence before filling that order. ALJ-90, at 24 (citing *Masters Pharm., Inc.*, 80 Fed. Reg. at 55479 n.164). Thus, as the DEA explained in its September 2006 letter to distributors, the obligation to report a suspicious order is in addition to the general requirement that a distributor maintain effective controls against diversion. ALJ-90, at 24. Thus, "the obligation to perform due diligence is ongoing throughout the course of a distributor[']s relationship with its customer." *Id.* at 25 (quoting *Masters Pharm., Inc.*, 80 Fed. Reg. at 55477). Furthermore, documenting the distributor's due diligence efforts is an essential part of maintaining effective controls against diversion. ALJ-90, at 25-26 (citing *Masters Pharm., Inc.*, 80 Fed. Reg. at 55428 n.21). In fact, the absence of documentation can serve as substantial evidence that a distributor did not perform the required due diligence. ALJ-90, at 26 (citing *Masters Pharm., Inc.*, 80 Fed. Reg. at 55428).

Respondent Failed to Conduct Adequate Due Diligence

The Government argues that the Respondent was plainly aware of its obligation to conduct due diligence. ALJ-90, at 29. The Respondent was also aware of what to look for, concerns such as: the trinity drug cocktail; the ratio of cash payments; the ratio of controlled substances dispensed; and excessive growth and dispensing of controlled substances. *Id.* at 30-31. Furthermore, the Respondent was routinely aware of its customer's performance in these areas because that performance was highlighted in the Pro-Compliance Reports the Respondent received. *Id.* at 31. In spite of the Respondent's awareness of these areas of concern, it did not conduct meaningful due diligence, and it did not document any explanations it may have received from its customer pharmacies. *Id.* The Respondent's conduct concerning the eight exemplar pharmacies illustrate the point. *Id.* at 32.

Hephzibah is one of the exemplar pharmacies. ALJ-90, at 32. When Hephzibah sought to open an account in March 2017, a Pro-Compliance Report was prepared. *Id.* That report showed that Hephzibah was dispensing a disproportionate amount of controlled substances; that an excessive amount of prescriptions were paid for in cash; that Hephzibah was dispensing high

quantities of both oxycodone and hydrocodone; that Hephzibah was filling prescriptions for practitioners whose DEA registration numbers could not be verified; and that Hephzibah was dispensing trinity drug cocktails. *Id.* at 32-33. In the Government's view, each of these issues raised a serious doubt about the legality of Hephzibah's business practices. *Id.* at 33. The Respondent, however, began shipping controlled substances to Hephzibah without restriction. *Id.* The Pro-Compliance Reports concerning the other exemplar pharmacies revealed similar concerns that the Respondent did not resolve. *Id.* at 34-35. Thus, the Respondent elected to "ignore information which raise[d] serious doubt as to the legality of a potential or existing customer's business practices." *Id.* at 36 (alteration in original) (quoting *Masters Pharm., Inc.*, 80 Fed. Reg. at 55477).

Respondent Failed to Detect and Report Suspicious Orders

The Government argues that despite being advised of its obligation to design and operate a system to detect suspicious orders, the Respondent made no effort to implement such a system until 2016. ALJ-90, at 37. As a result, there can be no serious dispute that the Respondent failed to comply with its obligations under 21 C.F.R. § 1301.74(b). *Id.* Furthermore, even after the Respondent established standard operating procedures in 2016, the Respondent apparently failed to follow its own procedures. *Id.* For example, those procedures required a daily drug sales report, but the Respondent produced no such report. *Id.* Those procedures also called for the Respondent to ask a customer pharmacy for a written explanation of an unusual order, but the Respondent produced no such written explanations. *Id.* Those procedures also stated that in all cases a letter would be sent to the DEA indicating a suspicious order, but the Respondent produced no such letters. *Id.* at 37-38.

In addition, the Government's reasonable and reliable statistical analysis demonstrated that between January 2014 and April 2018 the Respondent should have flagged around 12,000 orders for either oxycodone or hydrocodone as being potentially suspicious. ALJ-90, at 38, 40-44. There is no evidence in the record, however, that the Respondent identified, held, or investigated any of these potentially suspicious orders to dispel the indicia of suspiciousness. *Id.* at 38-39. It is thus fair to conclude that the Respondent was required to report all of these orders to the DEA. *Id.* at 39.

Mr. Irelan Cannot Accept Responsibility for Respondent

While the Government cites to 21 C.F.R. § 1316.50, it also acknowledges that it is not aware of any Agency decisions that address the question of who can accept responsibility on behalf of a corporate registrant. ALJ-90, at 46. Nevertheless, the Government argues that Mr. Irelan does not have standing to do so. *Id.*

The Government argues that a critical part of a registrant's burden is to "present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility carried by such a registration." ALJ-90, at 47 (quoting *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 363, 387 (2008)). In addition, the Government notes that "because past performance is the best predictor of future performance, this Agency has repeatedly held that . . . the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct." *Id.* (citing *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. at 387; *Sun & Lake Pharmacy*, 76 Fed. Reg. 24523, 24533 (2011)). The Government also argues that an essential element of that showing is that the registrant and its principals accept responsibility for their misconduct. ALJ-90, at 47. Thus, the Government argues, the issue is whether the Respondent and its principals have accepted responsibility for the Respondent's wrongdoing. *Id.* at 48.

The Government argues that Mr. Irelan lacks credibility to demonstrate the Respondent's acceptance of responsibility. ALJ-90, at 48. Mr. Irelan lacks credibility because he is neither an owner nor a corporate officer of the Respondent, which is owned by the Dickson family. *Id.* Instead, Mr. Irelan can be removed at will by that family, and the DEA has long recognized that it can look beyond the corporate veil to determine who makes the decisions concerning the controlled substance business. *Id.* at 48-49. Mr. Irelan also lacks credibility because during the period of misconduct the decisions concerning the Respondent's compliance were made by members of the Dickson family, and the corporate ownership and leadership remains the same today as it did during the period of misconduct. *Id.* at 49.[29]

The Government also argues that Mr. Irelan's acceptance of responsibility was equivocal. ALJ-90, at 50-54. As an initial matter, the Government argues that Mr. Irelan did not understand what he was accepting responsibility for. *Id.* at 50. Citing *Pharmacy Doctors Enterprises*, 83

[29] The Government also asks that I draw an adverse inference from Paul Dickson's failure to testify. ALJ-90, at 49 n.24.

Fed. Reg. 10876, 10903 (2018), the Government argues that there can be no acceptance of responsibility where there is no understanding about how a registrant's conduct fell short of federal standards. ALJ-90, at 50. As evidence of Mr. Irelan's lack of understanding, the Government argues that he was not prepared to address the specific allegations in the charging document. *Id.* at 51.

The Government argues that Mr. Irelan's testimony was limited to three areas: failure to apply due diligence information at the order level; a general acknowledgement that the Respondent's SOM system was not consistent with best practices and compliance; and the Respondent's failure to report suspicious orders. ALJ-90, at 51-52. In the Government's view, Mr. Irelan did not accept responsibility for the Respondent's failure to conduct adequate due diligence to resolve the numerous red flags identified in the Pro-Compliance Reports. *Id.* at 52. In addition, Mr. Irelan's purported acceptance of responsibility was equivocal and at times vague. *Id.* at 53. Finally, the Government argues that since the Respondent has not tendered an unequivocal acceptance of responsibility, its remedial actions are not relevant in these proceedings. *Id.* at 54.

Egregiousness and Deterrence

The Government argues that the Respondent's violations of the Controlled Substances Act and DEA regulations are so egregious that they outweigh any acceptance of responsibility and/or the Respondent's efforts at remediation. ALJ-90, at 58-60. Here, the Government cites to the tens of millions of dosage units of oxycodone and hydrocodone that the Respondent shipped to its customers, when it had ample reason to believe that those customers were engaging in illegitimate behavior. *Id.* at 59. Further, whether the Respondent became aware that its customers were engaged in suspicious practices, either through the Pro-Compliance Reports or from its own employees, or from the orders themselves, the Respondent ignored the information and continued to ship out orders. *Id.* at 59-60.

Finally, the Government argues that DEA's oversight responsibilities include both specific and general deterrence considerations. ALJ-90, at 60-61. Given the egregious nature of the Respondent's violations, the Agency's interest in deterring similar behavior among the regulated community weighs heavily in favor of revocation. *Id.* at 61 (citing *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74800, 74810 (2015)).

II. The Respondent's Position

The Respondent presented its position in an opening statement, Tr. 30-43, and in its Proposed Findings of Fact and Conclusions of Law ("Respondent's Brief"), submitted on August 2, 2019.[30] I have read and considered the Respondent's opening statement, and its post-hearing brief, in preparing this Recommended Decision.

In its Brief, the Respondent's proposed findings of fact are essentially the same as the Findings of Fact set forth in this Recommended Decision. ALJ-89, at 4-59, paras. 1-180. To the extent the Findings of Fact in this Recommended Decision differ from those proposed by the Respondent, the difference is because I have found the Respondent's proposed findings to be in error or not relevant to resolve the issues in this case. I specifically reject some of the Respondent's proposed findings of fact.[31] In addition, many of the Respondent's proposed findings of fact are based upon exhibits that contain statements about what the Respondent claims it did in the past, without any other evidence of record to corroborate those claims.[32] The Respondent also noted that there was no evidence presented concerning its New Orleans' registration. *Id.* at 2-3, and 11, para. 27.

The Respondent argues that the DEA failed to meet its burden that the Respondent's continued registration is not in the public's interest. ALJ-89, at 86-87, paras. 244-46. The Respondent also argues that due process requires the Tribunal to consider only the allegations

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[30] The Respondent's Brief has been marked as ALJ-89.

[31] For example, the Respondent relies on Respondent Exhibit 32 (for identification) in support of its position that Mr. Irelan had the authority to speak on the Respondent's behalf. Respondent refers to this proposed exhibit as 52 but it was marked for identification at the hearing as 32. Tr. 1077. That proposed exhibit was created and offered after Mr. Irelan testified and was not admitted. Tr. 1070-73. The proposed exhibit has no evidentiary value. Thus, it cannot be used to support the Respondent's proposed findings of fact, or its proposed conclusions of law. *See* ALJ-89, at 12, para. 32; at 65, para. 194; at 67, para. 198. In addition, Respondent Exhibit 5.001 (for identification), was never offered as an exhibit or admitted. ALJ-89, at 80, para. 231. Thus, it cannot be used to support the Respondent's conclusions of law. The same is true for Respondent's proposed exhibit 22. *Id.* at 63-64, para. 192.

[32] Examples of the Respondent creating a "fact" out of a document reporting that the Respondent did or did not do something are too pervasive to list. As examples, however, the Respondent's proposed findings of fact 34, 36-38, and 42-45 all cite to Government Exhibit 71, which clearly is a hearsay statement. The Respondent uses Government Exhibit 71 as proof of the actions the document says were performed. The same can be said of the Respondent's use of Government Exhibits 9, 11, 13, 18, 19. Indeed, the Respondent acknowledges this. The Respondent states that no DEA witness called into question the veracity of the Respondent's "descriptions of its suspicious order monitoring system provided to DEA in Respondent's responses to the Subpoenas." ALJ-89, at 15, para. 36 (emphasis added). Since the Respondent called no witness who could testify to the truth of the matters stated in the responses, I give little weight to proposed findings of fact that the Respondent did or did not take an action described in those responses, absent some corroborating evidence. For example, no evidence corroborates the Respondent's claim that it "ceased supplying 142 retail pharmacies," GE-9, at 5, but Government Exhibit 14 and its content provides some corroboration to the Respondent's claim that Government Exhibit 14 is a "phone log . . . kept by Clara Guin," GE-13, at 1.

regarding the Respondent's conduct in relation to the exemplar pharmacies in the OSC ("OSC Customers"). *Id.* at 88-89, paras. 248-50. According to the Respondent, the Government clearly indicated that the scope of its allegations regarding due diligence was limited to the OSC Customers. ALJ-89, at 89, para. 250. Thus, the Respondent's position is that the Tribunal should assume that all other conduct was lawful. *Id.* (citing *Wesley Pope, M.D.*, 82 Fed. Reg. 14944, 14984 (2017)). Therefore, the Respondent argues that the Government should be estopped from making any argument that the Respondent did not conduct due diligence relating to customers not identified in the OSC.[33] *Id.*

Nevertheless, the Respondent also argues that I incorrectly excluded evidence of due diligence documents unrelated to the OSC Customers.[34] ALJ-89, at 90-93, paras. 251-56. Specifically, the Respondent argues that the Tribunal's exclusion of attachments to Government Exhibit 9 was an error. ALJ-89, at 90, para. 252. The Respondent argues that the two exhibits were relevant and their authenticity was proven. ALJ-89, at 90-93.

Suspicious Orders

The Respondent argues that the Government failed to prove that it did not file suspicious order reports to the extent alleged in the OSC, and that the Government did not show that the orders met the regulatory definition of suspiciousness. ALJ-89, at 93-96, paras. 257-62. According to the Respondent, Mr. Rose's analysis was flawed and he utilized an unnecessarily rigid formula to try to prove that the Respondent did not conduct due diligence. ALJ-89, at 94-95, paras. 259-61. The Respondent argues that Mr. Rose's testimony should not be relied upon

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[33] To the extent the Respondent argues it was not on notice of general allegations of its failure to conduct due diligence, or that the testimony of Mr. Rose concerning a "ballpark" number was a new allegation, I reject the arguments. *See* ALJ-89, at 88-89, paras. 248-50; at 96-97, para. 263-64. First, "[a]n agency is not required to give every respondent a complete bill of particulars as to every allegation that [the respondent] will confront." *Brian Thomas Nichol, M.D.*, 83 Fed. Reg. 47352, 47353 n.3 (2018) (quoting *Moore Clinical Trials, L.L.C.*, 79 Fed. Reg. 40145, 40159 n.34 (2014)). The allegations are "not judged by the standards applied to an indictment at criminal law." *Id.* Furthermore, paragraph 10 of the OSC clearly put the Respondent on notice with regard to general allegations of due diligence, not simply limited to the exemplar pharmacies. ALJ-1, at 3, para. 10. With regard to Mr. Rose's use of the phrase "ballpark" number, that testimony did not give rise to a new allegation. Mr. Rose is a statistician and he was simply describing what he was doing in layman's terms. Second, I find that if there was any confusion on the Respondent's part that as the hearing progressed there was clearly litigation by consent. *See Superior Pharmacy I & Superior Pharmacy II*, 81 Fed. Reg. 31310, 31321 n.14 (2016) (citing *Duane v. Dep't of Defense*, 275 F.3d 988, 995 (10th Cir. 2002)); *see also Grider Drug #1 & Grider Drug #2*, 77 Fed. Reg. 44070, 44077 n.23 (2012).

[34] I do not concede that I erred in excluding the attachments the Respondent offered to Government Exhibit 9, attachments the witness could not identify and which contained no relevant information. I can state, however, that their exclusion had absolutely no impact on my recommendation in this case. Nevertheless, the excluded documents are certified as part of the Administrative Record.

did not consider "context"; and was not intended to identify suspicious orders. *Id.* at 93-94, paras. 258-60. Furthermore, a distributor is not required to perform a statistical analysis of every order to determine whether it is suspicious. *Id.* at 95, para. 261 (citing *Masters Pharm., Inc.*, 80 Fed. Reg. at 55418).

With respect to what the Respondent terms the Ballpark Theory—i.e., the Government's use of "ballpark numbers" or "how many suspicious orders could theoretically have been missed"—the Respondent claims that the theory was raised for the first time at the hearing and the Respondent was not timely notified of these allegations. ALJ-89, at 96-97, para. 263. Moreover, the Respondent argues that these allegations of theoretically suspicious orders were not proven by a preponderance of the evidence. *Id.* at 97, para. 264. In fact, the Respondent argues that "[a] generalized accusation of a wide-ranging failure to file non-specific reports does not meet the Government's burden of establishing by a preponderance of the evidence which orders were suspicious under DEA regulations." *Id.* at 94, para. 259.

Red Flags

The Respondent argues that Group Supervisor Dunn incorrectly defined red flags. ALJ-89, at 97, para. 265. Specifically, the Respondent cites to the record where the Group Supervisor testified that a ratio of controlled substance dispensing to non-controlled substance dispensing exceeding 15% constitutes a red flag, but then conceded that the Agency has indicated the ratio is 20 percent. ALJ-89, at 97, para. 265. Further, the Respondent quoted the Group Supervisor's testimony "that a distributor must investigate and resolve all red flags related to a customer or a customer's orders before shipping any controlled substances to that customer." *Id.* at 98-99, para. 267. Mr. Weinstein, however, testified "that he was not aware of 'any guidance on red flags of dispensing diversion that state that a distributor cannot make subsequent shipments of controlled substances.'" *Id.* In addition, Mr. Milione testified "that a distributor does not have to stop shipping all controlled substances orders to a pharmacy that exhibits a customer-level, rather than order-level red flag." *Id.* According to the Respondent, these differences in testimony demonstrate that the Group Supervisor's standards were not instructive on how red flags were to be addressed. *Id.* In the Respondent's view, the Group Supervisor's standards would completely disrupt the supply of legitimate medicine.[35] *Id.*

[35] The Respondent states, "[i]f distributors were to cease shipping all controlled substance orders to pharmacy customers during the pendency of an investigation into a customer-level red flag unconnected to a particular order,

The Government Did Not Prove that Respondent Failed to Conduct Due Diligence

The Respondent next argues that the Government did not prove that it failed to conduct due diligence before shipping orders, either through testimony or documentary evidence. ALJ-89, at 100-03, paras. 269-76. When Group Supervisor Dunn was asked whether he knew if the Respondent "dispelled any red flags," he testified, "Without having the documentation, I wouldn't." *Id.* at 100, para. 270. Also, the Respondent argues that the Group Supervisor acknowledged that the DEA received documents demonstrating due diligence, and that in a prehearing filing, the Government's proposed testimony included the Group Supervisor's proposed testimony that "DEA requested that Respondent provide DEA with its written due diligence files, including these written explanations, and Respondent did not provide any such files or explanations."[36] *Id.* at 100, para. 271. Thus, according to the Respondent, the Group Supervisor's testimony that the DEA received documents from the Respondent is inconsistent with the allegation that it did not perform due diligence. *Id.* at 101, para. 271. The Respondent argues that because the Group Supervisor does not know whether the Respondent conducted due diligence, the Government cannot meet the preponderance of evidence standard to show that it did not. *Id.*

The Respondent also argues that the Government cannot rely on evidentiary presumptions to establish that the Respondent did not perform due diligence. ALJ-89, at 101, para. 272. Recognizing language from *Masters Pharm. Inc.*, that "[t]he absence of an entry, where an entry would naturally have been made if a transaction had occurred, should ordinarily be equivalent to an assertion that no such transaction occurred, and therefore should be admissible in evidence for that purpose," the Respondent argues that presumption does not apply in this case. *Id.* (quoting *Masters Pharm., Inc.*, 80 Fed. Reg. at 55428). The Respondent argues that this presumption does not apply because the "Respondent did not have a standard practice of documenting the due diligence it performed after receiving information that either an order or a customer might be suspicious." *Id.* at 101-03, paras. 272-74.

No Requirement to Cease Shipments

Similarly, the Respondent argues that there is no DEA rule or regulation that requires registrants to suspend all shipments to a customer while it investigates red flags. ALJ-89, at 104,

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then the supply of legitimate medicine would be 'completely disrupt[ed].'" ALJ-89, at 99, para. 267 (alteration in original). While that may be true, it is also apparently what the Respondent now does. FF 299.

[36] Prehearing statements, however, do not constitute substantive evidence. Tr. 8.

para. 277. The Respondent argues that the Administrator's decision in *Southwood Pharm., Inc.*, 72 Fed. Reg. 36487 (2007) stated that the registrant's actions of shipping to its customers while investigating red flags was considered as merely a factor but did not impose a regulatory duty on the Respondent to stop shipments altogether. *Id.* at para. 278. The Respondent further distinguishes the facts of *Southwood Pharm., Inc.*, where the registrant continued to make shipments even after the DEA informed it that its customers were under investigation. *Id.* at 104-05, para. 279. The Respondent argues that the red flags the Government claims were known to the Respondent, "were insufficient to impose on Respondent a duty to stop shipping all controlled substances to the OSC Customers." *Id.* at 105, para. 280.

The Respondent argues that there are three differences in the red flags the Government identified in this case as opposed to the facts in *Southwood Pharm., Inc.* ALJ-89, at 105, para. 280. First, the DEA never informed the Respondent that the OSC Customers were being targeted. *Id.* at 105-06, para. 281. Second, DEA did not prove that the Respondent did not dispel the suspicions concerning the red flags. *Id.* at 106, para. 282. Third, the Group Supervisor's testimony concerning red flags should be called into question. *Id.* at 106-07, para. 283. Further, the Respondent urges the Tribunal to "ignore" the Group Supervisor's analysis of the Market Basket Reports because he (and those at DEA whom he supervised) did not understand whether the Reports "referred to dosage units, dollars, or both." *Id.* at 106-07, para. 283. The Group Supervisor's testimony concerning the Market Basket Reports is thus "unduly prejudicial" and "not probative of any fact." *Id.*

The Respondent next argues that the Group Supervisor's "testimony regarding the Pro Compliance reports does not establish that Respondent was aware of red flags sufficient to impose on it a duty to stop shipments." ALJ-89, at 107, para. 284. The Respondent contends that the Group Supervisor's testimony demonstrated that the Pro-Compliance Reports do not tell the whole story because: specialty drug stores could explain the high percentage of controlled substances; the drug store could be located close to a hospital; or "a high percentage of cash payments could be due to demographics such as a large uninsured population." *Id.* The Respondent also argues that the Group Supervisor's testimony that, from DEA's perspective, one trinity prescription would be too many, is unsupported by any published guidance documents or DEA decisions. *Id.* Instead, the Respondent points to testimony from Mr. Irelan, Mr. Milione,

and even the DEA Section Chief to argue that it did not have to cease shipments during investigations of customers. *Id.* at 107-08, para. 285.

The Respondent also argues that the Group Supervisor's "opinion, albeit expert, is not determinative" and contrary to both the Respondent's expert's findings and the practical realities of the pharmaceutical distribution business because his opinion contained unworkable thresholds. ALJ-89, at 108-09, paras. 286-87. Although the Respondent argues that the Government did not prove that the Respondent did not dispel red flags, it also argues that it did not fail to maintain effective controls against diversion. *Id.* at 109, para. 288. Moreover, (yet somewhat contradicting itself), the Respondent relies upon Mr. Irelan's acceptance of responsibility for the Respondent's failure to perform effective due diligence. *Id.*

Mr. Irelan's Authority to Accept Responsibility

The Respondent contends that it has unequivocally accepted responsibility for both the Government's proven and unproven allegations. *See* ALJ-89, at 60-61, para. 187. According to the Respondent, Mr. Irelan, its Controlled Substance Compliance Officer, is qualified to accept responsibility on behalf of the Respondent. ALJ-89, at 62, para. 188. In this matter, Mr. Irelan testified on behalf of the Respondent to accept responsibility for the underlying misconduct contained within the Government's allegations. *Id.* at 62, para. 189. The Respondent argues that Mr. Irelan is "better positioned than anyone,"[37] to accept responsibility on its behalf, because: (1) he is in charge of remedial steps;[38] (2) DEA precedent holds that "a senior person who oversees corporate operations that relate to a respondent's alleged misconduct is qualified to accept responsibility;"[39] and (3) he was authorized by the Chairman of the Board of Directors to accept responsibility.[40]

First, "Mr. Irelan testified that he would . . . be responsible for preventing reoccurrence of Respondent's failures to implement an appropriate suspicious order monitoring system," and "preventing reoccurrence of Respondent's failure to apply customer due diligence at the order level," and "preventing reoccurrence of Respondent's prior failure to report suspicious orders." ALJ-89, at 62, para. 189. Second, the Respondent argues that in *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316 (2012), the respondent provided the testimony of its Vice President of Pharmacy

[37] ALJ-89, at 63, para. 190.
[38] ALJ-89, at 62, paras. 188-89.
[39] ALJ-89, at 63-64, paras. 191-93.
[40] ALJ-89, at 65, para. 194. As noted earlier, I specifically reject this as a fact. *Supra* note 31.

Operations to accept responsibility, and the Administrator did not rule that he was unable or unqualified to do so. ALJ-89, at 63, para. 191. Thus, it is the Respondent's position that someone other than the owner or highest ranking executive may accept responsibility on behalf of the corporate registrant. *Id.* at 63, para. 192. According to the Respondent, in *Holiday CVS*, the DEA did not establish "which corporate officer can or cannot accept responsibility." *Id.* at 64, para. 193. The Respondent also argues that the Chairman of the Board of Directors explicitly authorized Mr. Irelan to accept responsibility on behalf of the Respondent. *Id.* at 64-65, para. 194; at 67, para. 198.

21 C.F.R. § 1316.50

The Respondent argues that the regulatory section relied upon by the Government, 21 C.F.R. § 1316.50, does not apply to the issue of acceptance of responsibility. ALJ-89, at 65, para. 195. Rather, the Respondent states that "the provision is intended to notify litigants of who is permitted to conduct litigation on behalf of a respondent." *Id.* at 65-66, para. 196.

The Respondent states that this provision "has never been cited to prevent a respondent's employee from accepting responsibility." ALJ-89, at 66, para. 196. Moreover, the Respondent states that it "clearly disclosed that Mr. Irelan would accept responsibility on behalf of Respondent for all proved allegations." *Id.* at para. 197. Accordingly, the Respondent argues, the Government waived its attempt to preclude the noticed testimony. *Id.*

Unequivocal Acceptance of Responsibility

The Respondent argues that it accepted responsibility through Mr. Irelan, who fully accepted responsibility for the Government's general allegations. ALJ-89, at 67-70, paras. 199-205. The Respondent also argues that the Government did not call into question his acceptance of responsibility during cross-examination. *Id.* at 67, para. 199. However, the Respondent acknowledges that Mr. Irelan did not accept responsibility for certain allegations. Specifically, the Respondent argues that the Government did not prove or even offer evidence concerning the allegations that no due diligence was performed on the "OSC Customers" after the Respondent became aware of red flags. *Id.* at 71, para. 208. The Respondent contends that both the Market Basket Reports and the Pro-Compliance Reports (discussed during the Group Supervisor's testimony) support this assertion. *Id.*

The Respondent notes that the Government failed to prove that the Respondent did not conduct additional due diligence on Wallace Drug Company after January 9, 2018. ALJ-89, at

72, para. 211. Accordingly, the Respondent argues that Mr. Irelan did not admit to the alleged misconduct in paragraph 29 of the OSC, or accept responsibility for those narrow allegations. *Id.* However, the Respondent does not believe that this refusal amounts to an equivocal acceptance of responsibility because the evidence shows that the Respondent conducted additional due diligence. *Id.* at para. 212. Further, the Respondent states that "Mr. Irelan has unequivocally accepted responsibility for Respondent's general failure to conduct effective due diligence" and this clear and confident acceptance of responsibility outweighs any equivocation on his part. *Id.* at 73, para. 214.

Next, the Respondent concedes that Mr. Irelan did not accept responsibility for not conducting additional due diligence on Bordelon's Super-Save Pharmacy ("Bordelon's") on or about May 2017 (ALJ-1, at para. 35). ALJ-89, at 73-74, para. 217. The Respondent offers the content of Government Exhibit 58, Market Basket Reports that post-date this time period and, which in the Respondent's estimation, constitutes evidence that it conducted additional due diligence. *Id.* at 74, para. 217. However, the Respondent accepted responsibility for the allegations contained in paragraph 39 of the OSC, as it pertained to its conduct with Bordelon's. *Id.* at para. 218. Specifically, paragraph 39 of the OSC begins with the language, "Notwithstanding the above," which incorporated the allegations of failing to conduct adequate due diligence and failing to file suspicious order reports. *Id.*

The Respondent also accepted responsibility for misconduct relating to: Folse Pharmacy, ALJ-89, at 74-75, paras. 219-20; Pharmacy Specialties Group, *id.* at 75-76, paras. 221-23, and Dave's Pharmacy, *id.* at 76-77, paras. 224-26. The Respondent acknowledges that Mr. Irelan testified that he was not knowledgeable enough to admit to paragraph 63 of the OSC. *Id.* at para. 224. The Respondent states, however, that Mr. Irelan's lack of knowledge does not render his testimony concerning paragraph 63 as an equivocal acceptance of responsibility. *Id.* at 77, para. 225. That is because Government Exhibit 61, the Market Basket Reports, and the testimony of the Group Supervisor, demonstrate that the Respondent conducted due diligence. *Id.* Because the Government did not prove this failure to conduct additional due diligence, the Respondent argues that Mr. Irelan's acceptance of responsibility remained unequivocal. *Id.* Further, Mr. Irelan also accepted responsibility for OSC paragraph 66, which encompassed the Dave's Pharmacy orders. *Id.* at para. 226.

The Respondent admits that Mr. Irelan testified that he was without full knowledge to accept responsibility for paragraph 73 of the OSC, which pertains to failing to conduct any additional due diligence concerning Hephzibah. ALJ-89, at 77-78, para. 227. Mr. Irelan, however, accepted responsibility for the other misconduct and again answered in the affirmative that he accepted responsibility. *Id.* The Respondent further argues that the Government failed to prove that it conducted no due diligence on Hephzibah Pharmacy. *Id.*

With respect to paragraph 82 of the OSC, pertaining to the Respondent's misconduct related to Wellness Pharmacy, the Respondent argues that it accepted responsibility for this conduct during the hearing. ALJ-89, at 78-79, para. 229. The Respondent also reiterated that the Government offered no evidence that the Respondent failed to conduct due diligence and in fact, the Group Supervisor testified that the Respondent indeed provided due diligence files in its responses to the DEA subpoenas. *Id.*

Similarly, the Respondent states that with regards to paragraph 91 of the OSC, containing allegations of misconduct related to Wilkinson Family Pharmacy, Mr. Irelan again did not admit the "unproven" allegation that it conducted no additional due diligence. ALJ-89, at 79, para. 230. The Respondent states that Government Exhibit 64, containing the Market Basket Reports for Wilkinson, post-dates the time period in which the misconduct occurred; also, the Group Supervisor testified that due diligence files were provided in the Respondent's subpoena responses. *Id.* at 80, para. 231.[41]

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[41] The Respondent also refers to Respondent Exhibit 5.001 to support its assertion that there is evidence of due diligence conducted on Wilkinson Family Pharmacy, but this exhibit was neither offered nor admitted into the record. *See* ALJ-89, at 80, para. 131 n.4. The Respondent seeks to admit this exhibit post-hearing, and the Respondent argues that this is appropriate because the "Respondent offered the exhibits, the Government had the opportunity to cross-examine witnesses about the exhibits, and introduce rebuttal testimony or evidence." ALJ-89, at 80, n.4 (citing *Brian Thomas Nichol, M.D.*, 83 Fed. Reg. 47352, 47353 n.4 (2018)). The Respondent, however, did not offer the exhibit into evidence. *See* Tr. 453-60. The statement of Respondent's counsel at the hearing that she "neglected to offer 5.001" did not clearly notify me at that time that she intended to formally move that document into evidence. Tr. 453. Furthermore, in *Nichol*, the respondent attempted to enter new exhibits into the record after the hearing had taken place; specifically, the respondent requested to enter back pages of certain DEA 222 forms to rebut the Government's testimony (and enter an accompanying affidavit of the individual who prepared the exhibit). 83 Fed. Reg. at 47353 n.4. The Administrator agreed with the ALJ's ruling to deny the admission of the Respondent's post-hearing proposed exhibit because the Respondent "had the originals of [the] exhibits at the hearing and made no attempt to offer" these copies. *Id.* (quoting the ALJ's Recommended Decision). In addition to timeliness, the ALJ and Administrator agreed that the proposed exhibit would be unfairly prejudicial to the Government due to the lack of opportunity to conduct cross-examination or present rebuttal evidence. *Id.* Therefore, it is apparent that the *Nichol* case does not provide a basis in which I can admit this exhibit post-hearing, absent the consent of the Government. This also applies to the "other documents about which there was an offer of proof but which the Tribunal did not receive in evidence." ALJ-89, at 80 n.4. Following past DEA cases, admitting

Public Interest Factors

The Respondent argues that its registration should not be revoked unless, after a five factor analysis, it is determined that it had committed such acts to render its registration inconsistent with the public interest. ALJ-89, at 110, para. 289. The Respondent then utilizes 21 U.S.C. § 823(b) as a procedural framework. *Id.* at para. 290. With respect to the first factor, maintaining effective controls against diversion, the Respondent notes that the Government did not produce any evidence concerning the Respondent's security practices. *Id.* at 111-12, paras. 292-94. Also concerning the first factor, the Respondent argues that it conducted due diligence of new customers and existing customers, noting that it was not as deficient as was the registrant in *Southwood Pharm., Inc.* *Id.* at 112, para. 295. As evidence that it conducted due diligence of new customers, the Respondent points out that a Pro-Compliance Report was commissioned on each new customer, and the Respondent's compliance officer analyzed the data contained in those reports. *Id.* at 112-13, para. 296. The Respondent also claims it terminated 142 customers as a result of its customer due diligence. *Id.* at 113, para. 297. The Respondent also routinely commissioned Pro-Compliance Reports and conducted its own Market Basket Reports on each existing customer. *Id.* at para. 298.

With respect to the second and fourth factors, the DEA should: consider whether the registrant has extensive experience in distributing controlled substances; whether the registrant has cooperated with the current and past DEA investigations; the number of years the registrant has distributed controlled substances; whether the registrant has received any warnings from the DEA; and if, after being warned, the registrant ignored the warning. ALJ-89, at 114-15, para. 301. In the Respondent's view, all of these considerations weigh in its favor. *Id.* at 115-17, paras. 302-03.

With respect to factors three and five, the Respondent argues that they weigh against revocation. *Id.* at 117-20, paras. 304-12. The Respondent noted that the Respondent and none of its principal officers have been convicted of any federal or state controlled substances laws. *Id.* at 117, para. 304. The Respondent also notes that none of the catch-all considerations of the fifth factor are applicable to this case. *Id.* at 118-20, paras. 306-12.

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these exhibits into evidence would be inappropriate. However, because Respondent's proposed Exhibit 5.001 was discussed on the record, I will forward it to the Administrator as part of the Administrative Record.

In conclusion, the Respondent argues that if its registration is revoked a "178 year-old American business will be destroyed." ALJ-89, at 121, para. 313. In its view, such a penalty would be "grossly disproportionate to the allegations in this case, devoid of support in the law, and undermine the public interest." *Id.* The Respondent further argues that although these proceedings are to be non-punitive, revocation in this case would constitute punishment. *Id.* at 122, para. 316. The Respondent asserts, "[n]o DEA regulation, guidance document, or precedent dictates that a fully-remediated registrant that has accepted responsibility to the extent that the Respondent has should have its DEA registration revoked." *Id.* Accordingly, the Respondent argues that its Certificates of Registration should not be revoked.[42] *Id.* at para. 317.

III. Analysis of Factor One: Maintenance of Effective Controls Against Diversion

The Order to Show Cause in this case is extensive. In essence, however, the OSC contains two significant allegations against the Respondent. First, it alleges that the Respondent failed to maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," in violation of 21 U.S.C. § 823(b)(1) and 21 C.F.R. § 1301.71(a). ALJ-1, at 3, paras. 7, 10. Second, the OSC alleges that the Respondent failed to adequately "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and report them to DEA, in violation of 21 C.F.R. § 1301.74(b). ALJ-1, at 3, paras. 8, 10. Thereafter, the OSC alleged specific examples of how the Respondent violated 21 U.S.C. § 823(b)(1) and 21 C.F.R. §§ 1301.71(a) and 1301.74(b). Some of those specific allegations were proven by the Government, while some were not.

The Government alleged that the Respondent failed to maintain effective controls against diversion by failing to report to DEA thousands of unusually large orders for hydrocodone and oxycodone and by shipping those orders without resolving red flags of diversion, ALJ-1, at 2, para. 2. Therefore, the allegations that the Respondent violated 21 U.S.C. § 823(b)(1) and 21 C.F.R. §§ 1301.71(a) and 1301.74(b) will be analyzed together.

The specific statutory language that the Respondent is alleged to have violated provides that:

> The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such

[42] The Respondent, however, did not discuss considerations of egregiousness and deterrence.

> registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered: (1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels . . . .

21 U.S.C. § 823(b)(1).[43] With respect to Factor One, concerning the maintenance of effective control against diversion, the DEA has promulgated regulations to guide the regulated community. Specifically,

> All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in [21 C.F.R.] §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.

21 C.F.R. § 1301.71(a). While there are no issues of physical security involved in this case, there are issues of operating procedures. One of DEA's security regulations addressed above, concerning operating procedures, is relevant in this case. It provides that:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74(b).

The Controlled Substances Act sets forth the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate . . . channels. . . ." as a factor to be considered in determining whether to issue a DEA registration to a distributor of controlled substances. 21 U.S.C. §§ 823(b)(1), (e)(1). All individuals or entities that are authorized by the DEA to handle controlled substances are required to "provide effective controls and procedures to guard against theft and diversion" of those substances. 21 C.F.R. § 1301.71(a). In furtherance of that overriding requirement the DEA's regulatory scheme

[43] 21 U.S.C. § 823(e) also applies to distributors of controlled substances. That section sets forth the identical factors to be considered regarding a registration to distribute controlled substances in schedules III, IV, and V, as are contained in 21 U.S.C. § 823(b) concerning schedules I and II. In addition, while these provisions speak of registering an applicant, it is appropriate to review the same factors when considering whether to revoke a registration. *See Zelideh I. Cordova-Velazco, M.D.*, 83 Fed. Reg. 62902, 62905 n.5 (2018) (holding that "the various grounds for revocation or suspension of an existing registration . . . are also properly considered in deciding whether to grant or deny a registration").

imposes three main obligations on distributors concerning controlled substances: (1) identify suspicious orders; (2) report suspicious orders to DEA; and (3) conduct due diligence of suspicious orders and red flags of diversion.

Identifying Suspicious Orders

To begin, the regulations require distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). The regulations provide that, at minimum, a suspicious order includes "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.* These three criteria are non-exclusive and registrants may encounter other considerations beyond those spelled out in the regulation, which could qualify an order as suspicious. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55473-74; *Masters Pharm., Inc.*, 861 F.3d at 221 (noting the regulatory criteria for suspicion are "exemplary rather than exhaustive"). For example, in addition to exhibiting the characteristics set forth in the regulation, a distributor might find a pharmacy's orders for controlled substances to be suspicious based upon the "pharmacy's business model, dispensing patterns, or other characteristics." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55473-74.

When a distributor's suspicious order monitoring system ("SOMS") places a hold on a customer's order for controlled substances because the order is of unusual size, pattern, or frequency, the order meets the specific criteria of being suspicious under 21 C.F.R. § 1301.74(b). *Masters Pharm., Inc.*, 80 Fed. Reg. at 55479; *Masters Pharm., Inc.*, 861 F.3d at 216-17 (affirming the Acting Administrator's ruling that "orders held by the [distributor's SOMS] met the regulatory definition of 'suspicious orders'"). The receipt of a suspicious order triggers two regulatory obligations: due diligence and reporting. First, if the distributor wants to ship the order, the distributor is required to investigate the order and determine whether there are any circumstances that dispel the suspicion before shipping it. *Id.* In other words, the distributor may not ship that suspicious order without exercising due diligence to resolve the suspicion. *Id.* at 55479 n.164. Shipping an order identified as suspicious is analogous to a practitioner prescribing a controlled substance to a patient, while ignoring the results of diagnostic tests that contraindicate the need for such a prescription. *Ralph J. Chambers, M.D.*, 79 Fed. Reg. 4962, 4970 (2014) (citing *United States v. Moore*, 423 U.S. 122, 135, 142-43 (1975)). Second, orders for controlled substances placed on hold by a distributor's SOMS meet the criteria of being

suspicious and the distributor is, therefore, required to report those orders to DEA under 21 C.F.R. § 1301.74(b). *Id.* at 55487 n.178.

In order to conclude that an order for controlled substances is suspicious, a "distributor is not required to establish, to a statistical certainty, that a pharmacy was likely diverting controlled substances." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55480. In fact, suspicion is a low standard, and is defined as merely one's "'apprehension or imagination of the existence of something wrong based only on inconclusive or slight evidence, or possibly no evidence.'" *Masters Pharm., Inc.*, 80 Fed. Reg. at 55478 (quoting Black's Law Dictionary 1585 (9th ed. 2009)). Thus, if a distributor is aware of any indication of "the existence of something wrong" concerning the size, frequency, or pattern of an order, the distributor is obligated to report it to the DEA. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55478. Because suspicion is a low standard, a distributor's obligation to report suspicious orders is triggered long before the distributor would have probable cause to believe that a customer is engaged in diversion. *Id.* As *Masters* explains, suspicion is not contingent on evidence that the order will be diverted or that the customer is engaged in diversion. *Id.* Stated differently, when it comes to the reporting requirement, the emphasis is on *suspicion*, and not conclusive proof of diversion. *Id.* at 55420 (explaining that tying suspicion to evidence of diversion "imposes a higher standard than that of the plain language of the regulation, which requires only that the order be suspicious").

Reporting Suspicious Orders

In addition to operating a system to identify suspicious orders, DEA regulations also obligate distributors of controlled substances to report to DEA all suspicious orders when such orders are discovered. 21 C.F.R. § 1301.74(b). In other words, DEA regulations require distributors like the Respondent "to alert DEA when their retail-pharmacy customers *attempt* to obtain unusual amounts of a controlled substance, because such attempts are powerful evidence that the pharmacies are operating illegally." *Masters Pharm., Inc.*, 861 F.3d at 217-18 (emphasis in original). A distributor is required to report any suspicious order, however, not just those of unusual size, frequency, or pattern. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55480 (finding that where the distributor had information that 50% of the drugs a pharmacy dispensed were controlled substances, that information raised a strong suspicion as to the legitimacy of the pharmacy's dispensing practices). Furthermore, filing ARCOS reports does not satisfy a

distributor's obligation to notify DEA of suspicious orders. *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36501.

The purpose of the DEA's reporting requirement is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55483 n.169 (quoting *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36501); FF 43. A distributor violates its regulatory obligation when it obtains "information that an order is suspicious but then chooses to ignore that information and fails to report the order." *Id.* at 55478. A distributor's obligation to notify DEA of suspicious orders is not unlike that cautionary advice frequently heard throughout this country's airports: "See Something, Say Something." If a distributor "sees something" that raises a suspicion concerning an order for controlled substances, the distributor must "say something" about it to the DEA.

The regulatory language concerning when a distributor is required to report a suspicious order is clear: the suspicious order must be reported to DEA "when discovered." 21 C.F.R. § 1301.74(b). Yet, the regulations do not elaborate on the meaning of "when discovered" or provide a deadline by which orders must be reported, leading to the question of how quickly after discovering a suspicious order must a distributor notify DEA. In the absence of regulatory guidance on this question, in *Masters* the Acting Administrator looked to a 2007 letter DEA issued to registrants. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55478. That letter, while not providing a hard deadline by which an order must be reported, explained that reports submitted pursuant to a routine schedule, such as daily, weekly, or monthly, do not satisfy the "when discovered" standard. *Id.*; *see also* GE-4, at 1-2 (a 2007 letter issued to registrants containing the same language as the letter cited in *Masters*). The letter's main point, however, was not to define the phrase "when discovered," but to inform registrants that submitting a list of shipped orders to DEA on a periodic schedule "does not meet the regulatory requirement to report suspicious orders." *Id.*; *see also* GE-4, at 1 (same). While the letter shed little light on the meaning of "when discovered," it did emphasize those two words. FF 2.

Thus, the most appropriate reading of the regulation is to take the plain, unambiguous language at face value: where the regulation instructs distributors to notify DEA of suspicious orders "when discovered," it means when the distributor first discovers that the order is suspicious. Furthermore, since suspicion has such a low threshold, "when discovered" occurs much earlier than when a distributor determines after an investigation that an order is either

legitimate or illegitimate. For example, just as soon as a distributor's SOM program puts a hold on an order, the order is suspicious and it must be reported. *Masters Pharm, Inc.*, 80 Fed. Reg. at 55418 n.178. Similarly, if a distributor finds cause to investigate an order, the order is already suspicious, as *Masters Pharm., Inc.*, explained that term. *Id.* at 55478. Accordingly, if a distributor finds a reason to investigate an order, that order has already met the criteria of suspiciousness for reporting purposes. *Id.* Therefore, the Government's suggestion that upon receipt of a suspicious order a distributor has two choices: (1) report and decline to fill; or (2) investigate and, if suspiciousness is dispelled, do not report (ALJ-90, at 22 n.8), is inconsistent with the plain language of 21 C.F.R. § 1301.74(b).

Conducting Due Diligence

"[I]n addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate . . . channels." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55421 (quoting letter dated September 27, 2006, issued by DEA to registered distributors); *see also* GE-3, at 2 (a letter dated September 27, 2006, containing the same language as the letter cited in *Masters*). A distributor's duty to perform due diligence on its customers is based upon the language in 21 C.F.R. § 1301.71(a) that a registrant "shall provide effective controls and procedures to guard against theft and diversion of controlled substances," as well as Factor One under 21 U.S.C. §§ 823(b) and (e). *Masters Pharm., Inc.*, 80 Fed. Reg. at 55477.

In conducting its due diligence of a customer, a distributor must do more than check the customer's DEA registration and state license; rather, it "must conduct a reasonable investigation 'to determine the nature of a potential customer's business before it' sells to the customer, and the distributor cannot ignore 'information which raise[s] serious doubt as to the legality of [a potential or existing customer's] business practices.'" *Masters Pharm., Inc.*, 80 Fed. Reg. at 55477 (alteration in original) (quoting *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36498). Furthermore, a distributor has a continuing obligation to perform due diligence of a customer throughout the distributor's relationship with the customer. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55477.

Although conducting due diligence is part of a distributor's obligation to maintain "effective controls and procedures" against diversion, 21 C.F.R. § 1301.71(a), the regulations themselves do not impose any requirement on distributors to document the due diligence that

they conduct. Despite the absence of any regulatory language concerning documentation of due diligence, in *Masters* the Acting Administrator reasoned that documentation is an indispensable component of the duty to maintain "*effective* controls" against diversion. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55428 n.21 (emphasis added). In essence, due diligence without documentation is ineffective due diligence and, in turn, is ineffective at guarding against diversion. "Even if [DEA] regulations do not require a distributor to document the reason provided by a customer to justify a suspicious order, documenting that reason is still an essential part of maintaining effective controls against diversion because subsequent events may provide information which shows that the reason was false." *Id.*

Further, the absence of documentation is evidence that the distributor did not determine whether there was justification for a suspicious order. *Masters Pharm., Inc.*, 861 F.3d at 218; *see also Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. 10876, 10887 (2018) (giving no weight to pharmacist's testimony that she resolved various red flags because she failed to produce documentary evidence to corroborate her claim); *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. 49816, 49835-36 (2016) (holding that while there is no requirement that a pharmacist document the resolution of a red flag on a prescription itself, the fact that the pharmacist did not do so is not conclusive proof that the pharmacist failed to resolve the red flag, but it is probative evidence of that failure); *Belinda R. Mori, N.P.*, 78 Fed. Reg. 36582, 36587 (2013) (noting that a practitioner's failure to create medical records for a patient can give rise to the inference that the practitioner had not examined the patient or performed periodic evaluations of the patient).

I, thus, reject the Respondent's argument that the absence of due diligence documentation cannot be considered as evidence that the Respondent did not conduct due diligence. ALJ-89, at 101, para. 272. The Respondent correctly notes that in *Masters Pharm., Inc.*, the registrant had told the DEA that it retained all of its due diligence records, and thus, the absence of those business records could be used to prove that due diligence had not been conducted. ALJ-89, at 101-03, paras. 272-75. The Respondent also argues that "unlike *Masters*, there is no evidence establishing that Respondent had a regularly conducted practice of making or keeping records of the results of diligence it performed . . . ." *Id.* at 102, para. 274. That argument is not exactly true. First, the Respondent's SOP Manual indicated that when investigating suspicious orders some customers would be "asked for a written explanation." FF 198. Second, the Respondent's written policy was to send a letter to the DEA concerning suspicious orders, along with

"customer supplied information" when available. *Id.* Third, the SOP Manual also described a monthly report, as well as a "daily controlled drug sales report" that were viewed by management. FF 196-97. Fourth, the Respondent kept a proprietary database in its ECP. RE-11, at 5. Thus, the Respondent had some procedures that would have documented some due diligence. Furthermore, the *Masters Pharm., Inc.* Final Order put the Respondent on notice in 2015 that documentation is essential. 80 Fed. Reg. at 55428 n.21 ("Even if the Agency's regulations do not require a distributor to document the reason provided by a customer to justify a suspicious order, documenting that reason is still an essential part of maintaining effective controls against diversion . . . ."). The Respondent, however, introduced little evidence that it resolved red flags or queried customers about suspicious orders. For example, the Respondent did not produce: any request to a pharmacy to provide a written explanation or any such written explanation; customer supplied information along with the three suspicious order reports it submitted; its own monthly report;[44] or a copy of its daily report of sales of controlled substances.

Additionally, adequate due diligence is much more than simply asking the pharmacy for an explanation. A distributor fails to conduct meaningful due diligence that satisfies its regulatory duties where it merely "accept[s] at face value whatever superficial explanation" the pharmacy offers and then fails to independently verify it. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55457. In addition, conducting due diligence and then failing to act on the findings is not due diligence. *See Southwood Pharm., Inc.*, 72 Fed. Reg. at 36500 (finding the distributor's due diligence efforts to be inadequate where the distributor possessed information that customers were diverting controlled substances yet the distributor continued to provide them with controlled substances); *see also Chambers, M.D.*, 79 Fed. Reg. at 4970 (finding that a doctor exceeds the bounds of professional practice: when he prescribes controlled substances without performing a physical exam, or where he performs an inadequate exam; where he ignores the results of tests; and where he takes no precautions to guard against drug abuse or diversion of controlled substances). Similarly, the Respondent excuses Mr. Irelan's inability to accept responsibility for failing to conduct additional due diligence because the Administrative Record

[44] While it is possible that this monthly report was the Market Basket Report, the Respondent never presented any evidence identifying it as such. If in fact the monthly report was the same as the Market Basket Report, it would have been reasonable for the Respondent to address this issue after the Group Supervisor testified that he had not seen one of the monthly reports in any of the documents the Respondent had produced in response to the DEA subpoenas. *See* FF 196.

contains evidence that the Respondent conducted Market Basket Reports concerning the exemplar pharmacies on a monthly basis. ALJ-89, at 71, para. 208. Nevertheless, there is scant evidence that the Respondent utilized the Market Basket Reports it compiled.

Red Flags

In addition to the requirement to identify and report individual suspicious orders, part of a distributor's duty to maintain "effective controls" against diversion, 21 C.F.R. § 1301.71(a), is to act on information, or red flags, indicative of diversion. To satisfy its duties as a registered distributor of controlled substances, a distributor "cannot ignore information it obtains that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer's business practices." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55478.

The term "red flag" is not defined in the CSA or DEA regulations. *JM Pharmacy Grp., Inc., d/b/a Farmacia Nueva & Best Pharma Corp*, 80 Fed. Reg. 28667, 28672 n.21 (2015). The term "red flag," however, has been used in DEA decisions as early as 1998 and in federal courts as far back as 1986. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. 79188, 79195 n.23 (2016), *pet. for rev. denied*, 881 F.3d 823 (11th Cir. 2018). In general, a red flag is any "circumstance that does or should raise a reasonable suspicion as to the validity of a prescription [or order]." *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. at 10896 n.31 (quoting *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. at 49839). Red flags are, in essence, "warning signs" or "suspicious circumstances" that alert the registrant that something is not right. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79195 n.23. One dictionary defines "red flag" as "'a sign of danger, a warning, or a signal to stop.'" *Id.* (quoting The Compact Edition of the Oxford English Dictionary 1132 (1987)).

There are numerous circumstances that "raise a reasonable suspicion as to the validity" of a pharmacy's dispensing of controlled substances. *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. at 10896 n.31. Such circumstances include a pharmacy that: dispenses a high volume of narcotics;[45] dispenses the trinity drug cocktail;[46] dispenses disproportionally

[45] *Masters Pharm., Inc.*, 80 Fed. Reg. at 5548-81 n.168 (explaining where a distributor had information that 50% of the prescriptions filled by a pharmacy were for controlled substances, and the average pharmacy only fills about 20%, the distributor "had substantial information which raised a strong suspicion as to the legitimacy of [the pharmacy's] dispensing practices"); GE-3, at 3.

more controlled substances than non-controlled substances;[47] fills prescriptions for a high volume of patients who pay for prescriptions in cash;[48] fills prescriptions for practitioners whose DEA registrations cannot be verified;[49] fills a disproportionate volume of controlled substance prescriptions written by only a few prescribers;[50] and orders excessive quantities of a limited variety of controlled substances.[51] FF 22.

A distributor fails to maintain effective controls against diversion where the distributor ships controlled substances to a pharmacy that exhibits red flags of diversion. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55457 (faulting the distributor for shipping controlled substances "while ignoring numerous red flags as to the legitimacy of the pharmacy's dispensing of controlled substances"); *cf. Top RX Pharmacy*, 78 Fed. Reg. 26069, 26082 (2013) (applying the same principle to pharmacies and explaining that a pharmacy may not fill a prescription in the face of a red flag unless the pharmacy has taken steps to resolve the red flag and ensure that the prescription is valid). Thus, supplying a pharmacy with controlled substances when the distributor is aware of red flags in the pharmacy's dispensing data is inconsistent with the distributor's obligation to guard against diversion. 21 U.S.C. §§ 823(b), (e); 21 C.F.R. § 1301.71(a).

Finally, if a distributor can be exempted from its obligation to report suspicious orders, the distributor's due diligence "must dispel all red flags indicative that a customer is engaged in diversion." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55478. "Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the [DEA] must be informed." *Id.*; *see also id.* at 55479 n.164 (same).

The following guidance from the D.C. Circuit Court of Appeals is instructive concerning a distributor's obligation to conform to DEA's due diligence and reporting requirements:

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[46] *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79194 ("The combination of a benzodiazepine, a narcotic and carisoprodol is 'well known in the pharmacy profession' as being used 'by patients abusing prescription drugs.'" (quoting *E. Main St. Pharmacy*, 75 Fed. Reg. 66149, 66163 (2010))).

[47] *Masters Pharm., Inc.*, 80 Fed. Reg. at 55421, 55456; GE-3, at 3.

[48] *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79194 ("'[A]ny reasonable pharmacist knows that a patient that (sic) wants to pay cash for a large quantity of controlled substances is immediately suspect.'" (quoting *E. Main St. Pharmacy*, 75 Fed. Reg. 66149, 66158 (2010))).

[49] FF 27.

[50] GE-3, at 3.

[51] *Masters Pharm., Inc.*, 80 Fed. Reg. at 55421; GE-3, at 3.

> As we have emphasized throughout this opinion, it is not necessary for a distributor of controlled substances to investigate suspicious orders if it reports them to DEA and declines to fill them. But if a distributor chooses to shoulder the burden of dispelling suspicion in the hopes of shipping any it finds to be non-suspicious, and the distributor uses something like the SOMS Protocol to guide its efforts, then the distributor must actually undertake the investigation. For example, when an employee uses the SOMS Protocol to confirm or dispel suspicion based on the amount of controlled medication the pharmacy is selling, the employee must request a 'UR,' *i.e.*, a document showing the pharmacy's 'actual dispensing[s] . . . of each drug.' [*Masters Pharm., Inc.*,] 80 Fed. Reg. [55418,] 55420 [(2015)]. Moreover, the investigating employee must 'document' customers' explanations for suspicious orders, so that he or she can verify those explanations and make sure they are consistent over time. *Id.* at 55,428 n.21. Additionally, if a customer's explanation for its order is 'inconsistent with other information the investigator has obtained about or from the customer, . . . the [investigator] must conduct 'additional investigation to determine whether [its customer is] filling legitimate prescriptions.' *Id.* at 55,477. Finally, the investigation must dispel all of the 'red flags' that gave rise to the suspicion that the customer was diverting controlled substances. *Id.* at 55,478. The Administrator recognized that, if investigating employees fail to take such basic steps, the SOMS (or similar protocol) does not function as an effective tool for dispelling suspicion.

Masters Pharm., Inc., 861 F.3d at 222-23. If nothing else, the D.C. Circuit made clear that all red flags must be resolved before shipping an order identified as suspicious.

Adverse Inference

In the face of the allegations contained in the OSC, the Respondent did not produce a single witness with first-hand knowledge of the Respondent's policies and procedures it may have actually utilized to conduct due diligence of its customers and to identify suspicious orders. While the Respondent did call Mr. Irelan, its current Director of Compliance, he did not take over that position until May 2018. FF 339. In fact, the position Irelan took was created just for him, and it did not even exist during the relevant time period. *Id.* Before taking the position of Director of Compliance, Mr. Irelan had no involvement in the Respondent's SOM program or the due diligence efforts the Respondent may have engaged in. FF 341-42. In fact, prior to May 2018, Mr. Irelan did not know what the term "red flag" meant. FF 342. Mr. Irelan's testimony concerning what the Respondent may have done concerning due diligence and identifying suspicious orders was based upon his review of the Respondent's records. FF 356.

Prior to the hearing, on August 3, 2018, the Respondent had summarized the proposed testimony of Paul M. Dickson, identified as the Respondent's President, and Clara Guin, who

was one of the individual's previously responsible for the Respondent's compliance program. ALJ-8, at 5-16; FF 207; RE-1, at 12. Then on September 12, 2018, the Respondent further elaborated on the expected content of Ms. Guin's proposed testimony. ALJ-15, at 2-5. On March 26, 2019, the Respondent once again provided a summary of Mr. Dickson's proposed testimony. ALJ-53. At the hearing, however, neither Mr. Dickson nor Ms. Guin testified. Respondent's counsel stated that Mr. Dickson was asserting his Fifth Amendment privilege and was unavailable. Tr. 1062. No explanation was provided as to why Ms. Guin did not testify. I note that Jacob Dickson was also responsible for the Respondent's compliance during the relevant time period. Tr. 807-09. He also did not testify.

The Government has asked that I draw an adverse inference "from the fact that the Dickson family sat silent in the face of accusation." ALJ-90, at 49 n.24. The Respondent does not directly address this point, but argues that the Government may not "rely on evidentiary presumptions to establish that Respondent did not perform due diligence on its customers." ALJ-89, at 101, para. 272. Its argument is more directed towards the absence of documentation.

Here, the Respondent elected not to present any testimony from anyone who was directly involved in the Respondent's alleged due diligence efforts and its purported efforts to identify suspicious orders from its customers, whether through some sort of statistical analysis or closely scrutinizing its customers' business and dispensing practices. At a DEA administrative hearing, it is permissible to draw an adverse inference from silence, even in the face of a Fifth Amendment invocation. *See Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005) (citing *United States v. Hale*, 422 U.S. 171, 176 (1975) ("[S]ilence gains more probative weight where it persists in the face of accusation, since it is assumed in such circumstances that the accused would be more likely than not to dispute an untrue accusation.")); *Joseph Baumstarck, M.D.*, 74 Fed. Reg. 17525, 17528 n. 3 (2009) (citing *Ohio Adult Parole Auth. v. Woodward*, 523 U.S. 272, 286 (1998)); *see also Kevin Dennis, M.D.*, 78 Fed. Reg. 52787, 52798 (2013) (holding that an adverse inference may be drawn where a practitioner does not challenge the accuracy of an allegation, even where the practitioner is not questioned about it); *T.J. McNichol, M.D.*, 77 Fed. Reg. 57133, 57150 (2012) (rejecting ALJ's decision not to apply an adverse inference from the respondent's failure to testify and concluded that the failure to testify warranted an inference that the respondent knowingly diverted controlled substances).

On the facts of this case, where the allegations are of a nature that a registrant, through its owners and/or its key employees, would be more likely than not to dispute them if untrue, an adverse inference based on the Respondent's silence is appropriate. Accordingly, as an evidentiary matter, it should be, and will be assumed that if Mr. Paul Dickson or Ms. Clara Guin, or any one of several members of the Dickson family or key employees of the Respondent who had first-hand knowledge of the Respondent's due diligence efforts had presented testimony, that testimony would have supported the Government's factual allegations.

The Respondent's Policies

In this case the Government alleged that the Respondent "consistently ignored and/or failed to implement its due diligence and suspicious order monitoring policies and failed to conduct meaningful due diligence into . . . orders to ensure that the controlled substances were not diverted." ALJ-1, at 3, para. 10. In addition, the Government alleged that the Respondent "failed to identify and report suspicious orders to DEA." ALJ-1, at 5, para. 21. To examine whether the Respondent either ignored or failed to implement its due diligence policy, an examination of the policy would be helpful.

During the course of DEA's investigation into the Respondent, the Respondent produced its Standard Operating Procedures Manual ("SOP Manual"), which was dated August 22, 2016, and its Policies & Procedures Manual for Prescription Drug Handling ("Policies & Procedure Manual") of February 2018. FF 70, 192, 203. Although the SOP Manual indicated that details of the Respondent's SOM program were "confidential and therefore are not made a part of this manual," it did detail that the Respondent "keeps a system in operation which is designed to discover those purchasing patterns of controlled substances which exceed the norm and could possibly be related to diversion activities." FF 193-94. To identify suspicious orders the SOP Manual outlines three methods the Respondent was to use: (1) Controlled Drug Volume Analysis Program; (2) Management Oversight; and (3) Employee Oversight. FF 195. The SOP Manual also stated that the Respondent's Controlled Drug Volume Analysis Program generated a monthly report that was reviewed by management. FF 196. In addition, under Management Oversight, the SOP Manual stated that "[a] daily controlled drug sales report is reviewed by management each day." FF 197. The SOP Manual envisioned that "[w]hen a suspicious pattern or purchase is identified by any of the above methods the customer is contacted in some but not all cases and asked for a written explanation for the unusual order. In all cases, a letter is sent to

the DEA indicating a possible suspicious order. Customer supplied information is included when available." FF 198.

In February 2018, the Respondent's Policies & Procedure Manual described its SOM program as "a three-fold approach to monitor all prescription drug and/or device orders, including unusual ordering patterns, amounts, and payments to identify any potential diversion or criminal activity." FF 204. As described, that three-fold approach included: Pro-Compliance Reports; Market Basket Reports; and input from Order Processing and Delivery Personnel. FF 205; *see also* FF 280. The Policies & Procedure Manual indicated that Pro-Compliance Reports were to be run annually or "more frequently as needed at the discretion of the Compliance officer." FF 206. Concerning the Market Basket Reports, the Policies & Procedure Manual mentions a "normal range" for controlled drug orders and that the Respondent's compliance officer "may stop shipment on any order if he or she finds the order to be unusually suspicious." FF 208-09. The Policies & Procedure Manual also referred to orders that diverge "from normal operations," but it did not define what was meant by "normal operations." FF 210.

The Respondent also provided information concerning its SOM program and its due diligence procedures in its responses to DEA subpoenas. FF 46-70. The Respondent informed the DEA that it utilized "a pro-active approach to avoid diversion of controlled drugs, including: screening new pharmacy customers; aggressively monitoring orders for controlled drugs; and eliminating pharmacy customers who fill orders for controlled drugs in excess of acceptable ratios, accept cash payments, prescribe the 'Holy Trinity' and/or other unacceptable practices." FF 49. The Respondent also asserted that it used a "four-fold approach to monitor all prescription drug orders and detect unusual ordering patterns, amounts, and cash payments to identify potentially suspicious orders." FF 51. The four-fold approach reportedly included: use of Pro-Compliance Reports; preparing a Market Basket Report of each customer on a monthly basis; since April 2017 use of software that identifies orders that are more than 10 times the "average dosage units ordered on a given drug on a certain day with the last 90 days of ordering patterns of the same drug"; the experience of the employees who fill the orders for controlled substances; and the input of delivery drivers and salesmen. *Id.* The Respondent also indicated that its "[o]n-the-ground employees often submit photos of the premises and photos of the store owner to the Compliance Officer." FF 53.

The Respondent also produced some of its due diligence files. FF 58. The Respondent asserted that it provided the DEA with "every Market Basket Report and Pro-Compliance Report in its records from January 1, 2016 to the present." FF 63. In fact, the Market Basket Reports for the eight exemplar pharmacies are contained in the Administrative Record. GE-57-64. The Respondent also provided the DEA with the January 5, 2016 through February 28, 2018 phone log of its former Compliance officer, Ms. Guin, submitting that some of the entries might relate to the subject of the DEA subpoena request concerning suspicious order reports and investigations. FF 67-68, 207. The Respondent also informed the DEA that "[d]uring the normal course of business, excessive orders which are the result of coding mistakes are dealt with promptly via telephone and such incidents are usually not documented." FF 63. The Respondent also asserted that its SOM program resulted in several investigations based on a software alert, review of Pro-Compliance and Market Basket Reports, as well as concerns raised by the Respondent's employees. *Id.* The Respondent also noted that prior to receipt of the DEA subpoenas the Respondent conducted investigations of "unusual or potentially suspicious orders via telephone calls . . . and by salesman in-store calls." *Id.*

The Respondent also informed the DEA that during the past decade it had "ceased supplying 142 retail pharmacies due to questions and concerns that the pharmacies were over-dispensing controlled substances." FF 55. Nevertheless, when the DEA asked the Respondent to provide copies of suspicious order reports it had submitted, the Respondent provided only two such reports, noting that it utilized "a pro-active approach to avoid diversion of controlled drugs." FF 49, 56. The Respondent then explained that it understood that the "DEA and applicable regulations do not require that a wholesale distributor maintain records of each and every internal investigation conducted on possible suspicious orders." FF 50.

The Respondent also presented a Power Point presentation of its SOM program to the DEA in August 2016. FF 337-38. During that presentation, the Respondent indicated that there were three components of its SOM program: Know your Customer – Enhanced Customer Profile ("ECP"); Order Monitoring; and External review of customer by third-party firm. RE-11, at 3. The Respondent briefed the DEA that as part of its ECP it kept "a proprietary database reserved solely for its SOM program. This database cover[ed] all areas pertinent to monitoring a customer for signs of suspicious orders or suspicious order patterns." RE-11, at 5. Under Order Monitoring, the Respondent indicated that it conducted ongoing internal review of the

purchasing habits of its customers. RE-11, at 8. The Respondent indicated that it conducted a "[c]ontinuous internal review . . . of the percentage of controlled substance items purchased by a pharmacy to that of total prescription items. This program also looks at trends in the pharmacy's purchasing patterns to detect any abnormal patterns of purchasing behavior." *Id.* The Respondent also indicated that it used Pro-Compliance Reports as a third-party review, and that it shared the results of these reports with its customers. RE-11, at 13, 15-16. Finally, the Respondent informed DEA that as a result of its SOM system it had ceased supplying controlled substances to 42 pharmacies from 2014 through 2016. FF 281; RE-11, at 14.

Failure to Maintain Effective Controls Against Diversion

The Government alleged that the Respondent failed to maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," in violation of 21 U.S.C. § 823(b)(1) and 21 C.F.R. § 1301.71(a). ALJ-1, at 3, paras. 7, 10. In support of that allegation, the Government presented evidence concerning eight of the Respondent's customer pharmacies, to demonstrate that the Respondent's due diligence was inadequate and that its controls against diversion were ineffective. The allegations include numerous instances where the Respondent failed to resolve red flags concerning each of the exemplar pharmacies.

***Folse Pharmacy* ("Folse")**

The Order to Show Cause ("OSC") alleged that the Respondent had received third-party vendor reports ("Pro-Compliance") concerning Folse. ALJ-1, at 8, para. 42. These reports indicated that a higher percentage than average of the prescriptions Folse filled were for controlled substances, and that a higher percentage than average of those prescriptions were paid for in cash. *Id.* The OSC also alleged that the Respondent's own Market Basket Reports concerning Folse revealed that a high percentage of Folse's total purchase volume was for controlled substances. ALJ-1, at 8, para. 43. The OSC alleged that the Pro-Compliance Reports and the Market Basket Reports identified red flags which the Respondent did not resolve. ALJ-1, at 8, para. 44. In addition, the Government alleged that between January 2014 and April 2018 the Respondent filled 58 unusually large orders for oxycodone and 68 unusually large orders for hydrocodone from Folse that the Respondent's due diligence failed to identify as suspicious and which the Respondent failed to report. ALJ-1, at 8-9, paras. 46-48; ALJ-52, at 20.

The Respondent received at least four Pro-Compliance Reports concerning Folse. FF 91, 95, 97, 100. Those reports show that of all the prescriptions Folse filled, the percentage of controlled substances ranged from 30 to 36 percent. *Id.* In addition, between September 2013 and November 2014, the number of dosage units of oxycodone that Folse dispensed increased by 11,759 dosage units. FF 93. The percentage of Folse's customers who paid cash for their controlled substances ranged from 18 to 41 percent. FF 92, 96, 98, 101. In September 2016, Folse dispensed 22 trinity drug cocktails and in June 2017 it dispensed 9 cocktails. FF 99, 102. Also, in June 2017 the number of dosage units of oxycodone and hydrocodone that Folse dispensed were both higher than the national average. FF 101. In addition, in June 2017, the DEA registration numbers of 23 practitioners who wrote prescriptions that Folse filled could not be verified. FF 103-04. In addition, three monthly Market Basket Reports that the Respondent prepared concerning Folse revealed that the percentage of controlled substances filled by Folse, when compared to all of the prescriptions it filled, ranged between 42 and 51 percent.[52] FF 105-07. There is no evidence that the Respondent suspended any shipments of controlled substances to Folse. FF 108. In fact, the Respondent supplied controlled substances to Folse from January 2014 through April 2018. Stip. 13.

***Bordelon's Super-Save Pharmacy* ("Bordelon's")**

The OSC alleged that the Respondent had received a Pro-Compliance Report concerning Bordelon's. ALJ-1, at 7, para. 34. That report indicated that Bordelon's dispensed a higher percentage than the national average of both oxycodone and hydrocodone. *Id.* The OSC alleged that the Pro-Compliance Report identified red flags which the Respondent did not resolve. ALJ-1, at 7, para. 35. In addition, the Government alleged that between January 2014 and April 2018 the Respondent filled 50 unusually large orders for oxycodone and 2 unusually large orders for hydrocodone from Bordelon's that the Respondent's due diligence failed to identify as suspicious and which the Respondent failed to report. ALJ-1, at 7-8, paras. 37-39; ALJ-52, at 20.

The Respondent received at least two Pro-Compliance Reports concerning Bordelon's. FF 109, 113. Those reports show that of all the prescriptions Bordelon's filled, the percentage of

[52] The Market Basket Reports do not indicate whether the percentage of controlled substances is based on dosages dispensed or on dollar value. Although Respondent's counsel, through questioning, implied that the percentage was based on dollar value, no evidence supports such a finding. I draw no conclusion on this issue as I have no evidence to support one. I simply note the percentage reported. *See* Tr. 408-09.

controlled substances was 17 percent. *Id.* In March 2017, Bordelon's dispensed 4 trinity drug cocktails. FF 112. Also, in March 2017 the number of dosage units of oxycodone and hydrocodone that Bordelon's dispensed were both higher than the national average. FF 109. In addition, in March 2017, the DEA registration numbers of 41 practitioners who wrote prescriptions that Bordelon's filled could not be verified. FF 110-11. In September 2017, the DEA numbers of 35 practitioners could not be verified. FF 114. There is no evidence that the Respondent suspended any shipments of controlled substances to Bordelon's. FF 116. Rather, the Respondent supplied controlled substances to Bordelon's from January 2014 through April 2018. Stip. 12.

***Wallace Drug Company* ("Wallace")**

The OSC alleged that the Respondent had received a Pro-Compliance Report concerning Wallace. ALJ-1, at 6, para. 26. That report indicated that Wallace dispensed a higher percentage than the national average of both oxycodone and hydrocodone, and that a higher percentage than average of Wallace's controlled substance prescriptions were paid for in cash. *Id.* The OSC alleged that the Pro-Compliance Report identified red flags which the Respondent did not resolve. ALJ-1, at 6, para. 27. The Government also alleged that between October 2017 and March 2018 the Respondent filled one unusually large order for oxycodone and six unusually large orders for hydrocodone from Wallace that the Respondent's due diligence failed to identify as suspicious and which the Respondent failed to report. ALJ-1, at 7, paras. 30, 32; ALJ-52, at 20. The Government also alleged that the Respondent ignored the concerns of its own employees who voiced concern about Wallace's hydrocodone orders on January 9, 2018, by shipping those orders. ALJ-1, at 6-7, paras. 28-29, 32.

The Respondent received at least one Pro-Compliance Report concerning Wallace. FF 117. That report shows that the percentage of Wallace's customers who paid cash for their controlled substances was 31 percent. *Id.* In August 2017, Wallace dispensed 3 trinity drug cocktails. FF 121. In addition, that same month, the DEA registration numbers of 23 practitioners who wrote prescriptions that Wallace filled could not be verified. FF 119-20. That report also shows that the number of dosage units of oxycodone and hydrocodone that Wallace dispensed were both higher than the national average. FF 118. In addition, four monthly Market Basket Reports that the Respondent prepared concerning Wallace between October 2017 and January 2018 revealed that the percentage of controlled substances filled by Wallace, when

compared to all of the prescriptions it filled, ranged between 23 and 37 percent. FF 122-25. Phone log entries of January 9, 2018, seemingly indicate that some of the Respondent's employees were concerned about the amount of hydrocodone Wallace was ordering. GE-14, at 31. That phone log also indicates that on January 9, 2018, the Respondent stopped a shipment to Wallace and requested that Wallace return some items already shipped, which Wallace apparently did. *Id.* Other than that phone log entry, there is no evidence that the Respondent suspended any shipments of controlled substances to Wallace. FF 126. In addition, the Respondent acknowledged that it supplied controlled substances to Wallace from October 2017 through April 2018. Stip. 11.

***Pharmacy Specialties Group* ("Pharmacy Specialties")**

The OSC alleged that the Respondent had received a Pro-Compliance Report concerning Pharmacy Specialties. ALJ-1, at 9, para. 51. That report indicated that Pharmacy Specialties dispensed a higher percentage than the national average of controlled substances, and that a higher percentage than average of Pharmacy Specialties' prescriptions for controlled substances were paid for in cash. *Id.* The OSC alleged that the Pro-Compliance Report identified red flags which the Respondent did not resolve. ALJ-1, at 9, para. 52. The Government also alleged that between January 2014 and April 2018 the Respondent filled 10 unusually large orders for oxycodone and 15 unusually large orders for hydrocodone from Pharmacy Specialties that the Respondent's due diligence failed to identify as suspicious and which the Respondent failed to report. ALJ-1, at 9-10, paras. 54-55, 59; ALJ-52, at 20. The Government also alleges that the Respondent also ignored the concerns of its own employees who voiced concern about Pharmacy Specialties' orders for controlled substances on March 7, 2017, (sic) and again on December 13, 2017, by shipping those orders. ALJ-1, at 10, paras. 56-59.

The Respondent received at least three Pro-Compliance Reports concerning Pharmacy Specialties. FF 127, 133, 137. Those reports show that of all the prescriptions Pharmacy Specialties filled, the percentage of controlled substances ranged from 18 to 30 percent. FF 127. The percentage of Pharmacy Specialties' customers who paid cash for their controlled substances ranged from 27-31%, and the June 2016 report specifically noted that 28% was higher than the national average. FF 128, 133, 137; GE-23, at 6. In addition, between February to October 2016, the number of dosages of hydrocodone that Pharmacy Specialties dispensed increased by 25 percent. FF 136. Further, between October 2016 and September 2017, the dosage units of

hydrocodone that Pharmacy Specialties dispensed increased by another 89%, and the number of dosage units of oxycodone increased by 148 percent. FF 138. In February 2016, Pharmacy Specialties dispensed two trinity drug cocktails, and in October 2016 it dispensed one. FF 132, 135. In addition, in February 2016, the DEA registration numbers of three practitioners, who wrote prescriptions that Pharmacy Specialties filled, could not be verified. FF 129-30. In fact, one of those numbers was a number for an application for a DEA registration. FF 131. In October 2016, the DEA registration numbers of 2 more practitioners who wrote prescriptions that Pharmacy Specialties filled could not be verified. FF 134. In addition, three monthly Market Basket Reports that the Respondent prepared concerning Pharmacy Specialties revealed that the percentage of controlled substances filled by Pharmacy Specialties, when compared to all of the prescriptions it filled, ranged between 27 and 52 percent. FF 139-41. While the Respondent's employees apparently raised concern on March 7, 2016, and on December 13, 2017, about orders for controlled substances that Pharmacy Specialties had placed, there is no evidence that the Respondent suspended any shipments of controlled substances to Pharmacy Specialties. FF 142. In fact, the Respondent acknowledged that it supplied controlled substances to Pharmacy Specialties from January 2014 through April 29, 2018. Stip. 14.

***Dave's Pharmacy* ("Dave's")**

The OSC alleged that the Respondent had received Pro-Compliance Reports concerning Dave's. ALJ-1, at 10-11, para. 62. Those reports indicated that Dave's presented a relatively high-risk to the Respondent. *Id.* The reports also indicated that Dave's dispensed a high quantity of hydrocodone and had high cash payments for controlled substances. *Id.* The OSC alleged that the Pro-Compliance Reports identified red flags which the Respondent did not resolve. ALJ-1, at 11, para. 63. In addition, the Government alleged that between January 2014 and April 2018 the Respondent filled 103 unusually large orders for oxycodone and 14 unusually large orders for hydrocodone from Dave's that the Respondent's due diligence failed to identify as suspicious and which the Respondent failed to report. ALJ-1, at 11, paras. 65-67; ALJ-52, at 20.

The March 2014 initial Pro-Compliance Report concerning Dave's indicated that the pharmacy represented a relatively high-risk to the Respondent, with one prescriber alone issuing 85 prescriptions for trinity cocktails. FF 143; GE-24, at 6. The Respondent received at least six Pro-Compliance Reports concerning Dave's. FF 143, 145, 150, 153, 156, 159. Those reports

show that of all the prescriptions Dave's filled, the percentage of controlled substances ranged from 20 to 23 percent. FF 143, 145, 149, 153, 156, 159. Those same reports reveal that the percentage of Dave's customers who paid cash for their controlled substances ranged from 17 to 35%, and the report of June 2017 specifically noted that 19% was above the national average. FF 144, 146, 150, 154, 156, 160; GE-24, at 24. In addition, between March 2014 and January 2015 the number of dosage units of oxycodone that Dave's dispensed increased by 12,105 dosages. FF 147. Then from May 2014 through December 2015 the number of dosages of oxycodone that Dave's dispensed increased by 205%, and it increased another 14% from June through November 2016. GE-24, at 19, 21. The Pro-Compliance Reports also informed the Respondent that Dave's dispensed numerous trinity cocktails: 57 from March 2014 through January 2015; 33 from December 2015 through June 2016; and 14 in June 2017. FF 149, 155, 162. In addition, in June 2017, the DEA registration numbers of 11 practitioners who wrote prescriptions that Dave's filled could not be verified. FF 161. In fact, of those 11 practitioners, 2 were reported to Dave's as having the same DEA registration number. FF 163. Further, in June 2017 the number of dosages of oxycodone and hydrocodone that Dave's dispensed were both higher than the national average. FF 159. In addition, the Respondent supplied controlled substances to Dave's from January 2014 through May 1, 2018, and there is no evidence that the Respondent suspended any shipments of controlled substances to Dave's. Stip. 15; FF 164.

***Hephzibah Pharmacy* ("Hephzibah")**

The OSC alleged that the Respondent had received a Pro-Compliance Report concerning Hephzibah. ALJ-1, at 11, para. 69. That report indicated that of the prescriptions that Hephzibah filled a higher percentage than average were for controlled substances, and that a large percentage of those prescriptions were paid for in cash. *Id.* The OSC alleged that the Pro-Compliance Report identified red flags which the Respondent did not resolve. ALJ-1, at 12, para. 70. The Government further alleged that the Respondent also ignored the concerns of its own employees who voiced concern about Hephzibah's need to clear up issues raised by the Pro-Compliance Report, including "high cash, trinity & high quantities on hydrocodone & oxycodone." ALJ-1, at 12, para. 72. Finally, in spite of the fact that the Respondent closed the Hephzibah account due to the Respondent's "due diligence efforts," the Respondent shipped all orders placed by Hephzibah and did not file a suspicious order report concerning any of Hephzibah's orders. ALJ-1, at 12, paras. 77-78.

The Respondent received at least one Pro-Compliance Report concerning Hephzibah. FF 165. That reports shows that of all the prescriptions Hephzibah filled in February 2017, 27% of them were for controlled substances, which was higher than the national average. *Id.* The report also documents that 36% of Hephzibah's customers paid cash for their controlled substances. FF 167. Hephzibah also filled 9 trinity drug cocktails in February 2017. FF 168. In addition, in February 2017, the DEA registration numbers of 20 practitioners who wrote prescriptions that Hephzibah filled could not be verified. GE-25, at 6. Also in that month, the number of dosage units of oxycodone and hydrocodone that Hephzibah dispensed were both higher than the national average. FF 165. Phone log notes of March 17, 2017, reflect that the Respondent's employees were concerned about the issues raised in the Pro-Compliance Report for Hephzibah. FF 169. Specifically, those notes reflect that Hephzibah needed to clean up issues concerning "high cash, trinity & high quantities on Hydrocodone & Oxycodone." *Id.* In other due diligence notes concerning Hephzibah, the Respondent indicated that the account was closed because Hephzibah "would rather change wholesalers than cooperate with our compliance program." FF 169. There is no evidence that the Respondent suspended any shipments of controlled substances to Hephzibah before closing its account. FF 170. The Respondent supplied Hephzibah with controlled substances from April 2017 through May 2017. Stip. 16.

***The Wellness Pharmacy* ("Wellness")**

The OSC alleged that the Respondent had received a Pro-Compliance Report concerning Wellness. ALJ-1, at 13, para. 80. That report indicated that of the prescriptions that Wellness filled a higher percentage than average were for controlled substances, and that Wellness dispensed high quantities of oxycodone and hydrocodone. *Id.* The OSC also alleged that the Respondent's own Market Basket Reports concerning Wellness revealed a high percentage of Wellness' total purchase volume was for controlled substances. ALJ-1, at 13, para. 81. The OSC alleged that the Pro-Compliance Reports and the Market Basket Reports identified red flags which the Respondent did not resolve. ALJ-1, at 13, para. 82. In addition, the Government alleged that between January 2014 and April 2018 the Respondent filled 119 unusually large orders for oxycodone and 3 unusually large orders for hydrocodone from Wellness that the Respondent's due diligence failed to identify as suspicious and which the Respondent failed to report. ALJ-1, at 13, paras. 84-85, 88; ALJ-52, at 20.

The Respondent received at least four Pro-Compliance Reports concerning Wellness. FF 171; GE-26, at 10-12. Those reports show that of all the prescriptions Wellness filled, the percentage of controlled substances ranged from 64-69%, and the initial report showed that 46% of all prescriptions Wellness dispensed were for either oxycodone or hydrocodone. FF 171. Further, in October 2017 the number of dosage units of oxycodone and hydrocodone that Wellness dispensed were both higher than the national average, and 91% of the controlled substances dispensed were Schedule II drugs. *Id.* In addition, the Respondent prepared two monthly Market Basket Reports concerning Wellness, one in January 2016 and the other in December 2017. FF 172-73. The first showed that 84% of all the prescriptions filled by Wellness were for controlled substances, and the other recorded 92 percent. *Id.* There is no evidence that the Respondent suspended any shipments of controlled substances to Wellness. FF 174. Between January 2014 and December 2017, the Respondent supplied Wellness with controlled substances. Stip. 17.

***Wilkinson Family Pharmacy* ("Wilkinson")**

The OSC alleged that the Respondent had received Pro-Compliance Reports concerning Wilkinson. ALJ-1, at 14, para. 90. Those reports indicated that of the prescriptions that Wilkinson filled a higher percentage than average were for controlled substances, that Wilkinson dispensed high quantities of oxycodone and hydrocodone, and that a large percentage of the controlled substances that Wilkinson dispensed were paid for with cash. *Id.* The OSC alleged that the Pro-Compliance Reports identified red flags that the Respondent did not resolve. ALJ-1, at 14, para. 91. In addition, the Government alleged that between January 2014 and April 2017 the Respondent filled 2 unusually large orders for oxycodone and 49 unusually large orders for hydrocodone from Wilkinson that the Respondent's due diligence failed to identify as suspicious and which the Respondent failed to report. ALJ-1, at 14, paras. 93, 96-97; ALJ-52, at 20.

The Respondent received at least five Pro-Compliance Reports concerning Wilkinson, and the initial report identified Wilkinson as "***high risk.***" FF 175, 178, 181, 184, 188. Those reports show that of all the prescriptions Wilkinson filled, the percentage of controlled substances ranged from 30-45%, and they were mainly Schedule II drugs. *Id.* Four of those same reports reveal that the percentage of Wilkinson's customers who paid cash for their

controlled substances ranged from 17 to 38 percent.[53] FF 176, 179, 182, 185. The Pro-Compliance Reports for Wilkinson also showed that the pharmacy had filled prescriptions for trinity cocktails: filling many in March 2014; 26 from March 2014 through January 2015; 21 from January 2015 through January 2016; and 20 from January through August 2016. FF 177, 180, 183, 187. Between January through August 2016, the number of dosage units of oxycodone that Wilkinson dispensed increased by 10 percent. FF 186. In addition, in January 2017 the number of dosage units of oxycodone and hydrocodone that Wilkinson dispensed were both higher than the national average. FF 188. Further, in January 2017, the DEA registration numbers of 46 practitioners who wrote prescriptions that Wilkinson filled could not be verified. FF 189. Finally, there is no evidence that the Respondent suspended any shipments of controlled substances to Wilkinson. FF 191. The Respondent did, however, supply controlled substances to Wilkinson from January 2014 through April 2017. Stip. 19; GE-64, at 31-40.

Analysis of the Evidence Concerning the Exemplar Pharmacies

With respect to the eight pharmacies discussed above, virtually every entry represents a red flag the Respondent was obligated to resolve before shipping controlled substances to the pharmacies. As a general rule, red flags for distributors include a pharmacy that: dispenses a high volume of narcotics; dispenses the trinity drug cocktail; dispenses disproportionally more controlled substances than non-controlled substances; fills prescriptions for a high volume of patients who pay for prescriptions in cash; fills prescriptions for practitioners whose DEA registrations cannot be verified; fills a disproportionate volume of controlled substance prescriptions written by only a few prescribers; and orders excessive quantities of a limited variety of controlled substances. FF 22.

Concerning dispensing controlled substances versus non-controlled substances, a pharmacy's suspicion should be aroused any time that percentage exceeds 15 percent. FF 23. In most instances addressed above, however, based on Pro-Compliance Reports the Respondent was aware of many percentages well above 20 percent, with a range between 14-68 percent.[54] The Respondent's own Market Basket Reports, as discussed above, revealed even higher percentages with a range between 23-92 percent. There is no persuasive evidence in the record

[53] The most recent Pro-Compliance Report for Wilkinson showed a cash payment of 14% for controlled substances. GE-27, at 25.

[54] One Pro-Compliance Report concerning Wallace in August 2017 shows controlled substances at 14 percent. GE-20, at 11.

that the Respondent performed any effective due diligence to determine whether there was a legitimate explanation for the pharmacies having high percentages of controlled substances when compared to the non-controlled substances the pharmacies dispensed.

With respect to cash payments for controlled substances, a pharmacy's suspicion should be aroused any time that percentage exceeds 9 percent. FF 24. In most instances addressed above, however, based on Pro-Compliance Reports the Respondent was aware of many percentages above 25%, within a range between 14-41 percent. There is no persuasive evidence in the record that the Respondent performed any effective due diligence to determine whether there was a legitimate explanation for the pharmacies accepting a high percentage of cash payments for the prescriptions for controlled substances they filled.

It is also a red flag when a pharmacy fills a combination of prescriptions that equate to a trinity drug cocktail. FF 22, 25-26. In a response to the DEA, the Respondent acknowledged its concern about trinity drug cocktails. FF 49. Nevertheless, concerning the eight pharmacies discussed above, the Pro-Compliance Reports informed the Respondent that seven of the pharmacies had been filling trinity drug cocktails, with reports ranging from 1 cocktail to 85 cocktails. Particularly troubling was the March 2016 report concerning Dave's. That Pro-Compliance Report advised the Respondent that Dave's had filled 85 trinity cocktail prescriptions, all written by the same practitioner. While the Respondent did contact Dave's, it apparently did not do so until almost a year later on February 16, 2017, and it is not possible to determine exactly what was discussed. FF 68; GE-14, at 23. In addition to the report of the 85 trinity drug cocktails, as detailed above, the Respondent was on notice of five additional reports of these pharmacies filling 20 or more trinity prescriptions: Dave's, an additional 57 and 23; Wilkinson, 26 and 20; and Folse, 22. Other than the one rather cryptic note in the Respondent's phone log concerning Dave's, however, there is no persuasive evidence in the record that the Respondent performed any effective due diligence to determine whether there were legitimate explanations for these customer pharmacies filling so many trinity prescriptions.

The Pro-Compliance Reports also informed the Respondent that seven of the above pharmacies were filling prescriptions written by practitioners whose DEA numbers could not be verified. Filling such prescriptions is a red flag. FF 22, 27. As detailed above, the range of unverified DEA numbers in the Pro-Compliance Reports was between 2 and 46, with 6 reports

indicating 20 or more DEA numbers that could not be verified.[55] While both Milione and Irelan testified that they learned that the DEA verification portion of the Pro-Compliance Report was not reliable, they both learned that information after the Order to Show Cause was issued. There is no persuasive evidence in the record that the Respondent performed any effective due diligence, or due diligence of any kind, to resolve the question of whether or why its customer pharmacies were filling prescriptions written by practitioners whose DEA registrations could not be verified.

It is also a red flag when a pharmacy dispenses a high volume of narcotics, or when it orders an excessive quantity of a limited variety of controlled substances. FF 22. The Pro-Compliance Reports concerning the eight pharmacies contain information that raised these red flags. For example, as discussed above, the reports specifically advised the Respondent that seven of the pharmacies' orders for both hydrocodone and oxycodone exceeded the national average. Those reports also informed the Respondent that of those seven pharmacies, the percentage of controlled substances those pharmacies dispensed compared to other prescriptions they filled was also well above the national average.

Although the Pro-Compliance Reports for the eighth pharmacy, Pharmacy Specialties, did not indicate that it was dispensing hydrocodone and oxycodone higher than the national average, it did report significant increases in its orders. For example, Pharmacy Specialties increased its purchases of hydrocodone by 25% between February to October 2016, and by another 89% between October 2016 and September 2017. During that later period, Pharmacy Specialties increased its orders for oxycodone by 148 percent. Dave's also had a significant increase in its dispensing of oxycodone: increasing by 12,000 dosages between March 2014 and January 2015; followed by an increase of 205% between May 2014 and December 2015; and another increase of 14% between June and November 2016. With regard to Folse, between September 2013 and November 2014 the number of dosage units of oxycodone it dispensed increased by over 11,000. Such increases are very big red flags. FF 28, 93. Here, there is no persuasive evidence in the record that the Respondent performed any effective due diligence to

[55] While some of the Pro-Compliance Reports contained on the CD-ROM exhibits submitted by the Government reflect far larger numbers of unverified DEA numbers, *see* FF 104, 114, 120, I have used the lower numbers because other portions of the reports actually list the names of the practitioners that correspond with the lower numbers. *Supra* notes 14 & 15.

resolve red flags concerning the high volume of controlled substances that these eight pharmacies were dispensing.

When a distributor receives a Pro-Compliance Report that raises red flags, the distributor should conduct additional due diligence concerning those red flags. FF 31; *Masters Pharm., Inc.*, 861 F.3d at 222-23. In fact, the presence of a red flag triggers a distributor's obligation to conduct due diligence. FF 30. When a distributor sees red flags on a Pro-Compliance Report, the distributor is obligated to exercise due diligence in investigating those red flags. *Id.* It is essential that a distributor document the resolution of red flags. FF 34; *Masters Pharm., Inc.*, 80 Fed. Reg. at 55428 n.21. In essence, due diligence without documentation is ineffective due diligence and, in turn, ineffective at guarding against diversion. In this case, except as noted, there is no documentation that the Respondent resolved the red flags addressed above.

The Respondent acknowledged the paucity of documentation to show that it had resolved red flags. FF 50, 54, 356, 357. Contrary to the Respondent's argument (ALJ-89, at 101-03, paras. 272-75), the absence of documentation of resolving red flags, however, is evidence that the red flags were never resolved. *Masters Pharm., Inc.*, 861 F.3d at 218. While the Respondent did conduct some due diligence, such as by obtaining Pro-Compliance Reports, and by preparing its own monthly Market Basket Reports of its customers, it is not enough to simply order the reports without taking appropriate action based on the content of those reports. *Chambers*, 79 Fed. Reg. at 4970 (citing *Moore*, 423 U.S. at 142-43). Further, while the Respondent had written policies and procedures, those policies and procedures only identified three suspicious orders over a period of four years and four months that were reported to the DEA. In addition, the Respondent's written policy was to contact customer pharmacies only in some, but not all, cases. FF 198. Quite obviously, as acknowledged by the Respondent, those procedures were not working. FF 277-79, 357; Tr. 720-21. The Respondent also had a policy of producing monthly and daily reports, yet none are in the Administrative Record. FF 196-97. In addition, the Respondent kept a proprietary database, RE-11, at 5, yet introduced no due diligence records from it. Thus, I agree with the assessment of the Group Supervisor, an expert witness, that even though the Respondent produced some due diligence files to DEA, a distributor "can conduct due diligence and ignore the red flags that are in [its] face and continue to ship. And that's what I feel like happened in this particular case." Tr. 463; *see also* Tr. 80 (testimony of Prevoznik: "[Y]ou can ask for all these things, but you have to do something with it."). And as the evidence

shows, the Respondent continued to ship controlled substances despite the red flags raised in those due diligence files, which makes the due diligence ineffective at guarding against diversion.

Finally, the Respondent produced no witness with first-hand information to rebut the allegations contained in the OSC. Specifically, the Government alleged that the Respondent "consistently ignored and/or failed to implement its due diligence and suspicious order monitoring policies and failed to conduct meaningful due diligence into . . . orders to ensure that the controlled substances were not diverted." ALJ-1, at 3, para. 10; at 5, para. 21. Therefore, it is appropriate to draw the adverse inference that if Mr. Paul Dickson or Ms. Clara Guin, or, for that matter, any one of several members of the Dickson family or key employees of the Respondent who had first-hand knowledge of the Respondent's due diligence efforts, had presented testimony, that testimony would have supported the Government's factual allegations.

Based on the above evaluation of the evidence concerning the exemplar pharmacies, I find that the allegations that the Respondent failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels in violation of 18 U.S.C. § 823(b)(1) and 21 C.F.R. § 1301.71(a), and that it failed to adequately design and operate a system to disclose to the registrant suspicious orders of controlled substances in violation of 21 C.F.R. § 1301.74(b), are **SUSTAINED.** Specifically, the allegations detailed above concerning the exemplar pharmacies, are **SUSTAINED.** These violations weigh in favor of revoking the Respondent's Certificates of Registration and denying any pending applications. Those allegations contained in the Order to Show Cause that the Respondent did not conduct **any** additional due diligence concerning the exemplar pharmacies, as set forth in paragraphs 27, 29, 35, 44, 52, 63, 70, 82, and 91 of the OSC, are **NOT SUSTAINED.**[56] Those allegations contained in the Order to Show Cause concerning the specific number of shipments, and the number of dosage units shipped to the exemplar

[56] The Government's own evidence disproves the allegation that the Respondent did not conduct *any* additional due diligence. The Respondent routinely prepared monthly Market Basket Reports concerning each exemplar pharmacy. GE-57-64; Tr. 423. In addition, the Respondent frequently obtained new Pro-Compliance Reports concerning these pharmacies, GE-20-56, and a Government expert acknowledged that those reports could be considered additional due diligence. Tr. 421.

pharmacies, as set forth in paragraphs 30, 36, 45, 53, 64, 71, 83, and 92, are **NOT SUSTAINED.**[57]

Failure to Report Suspicious Orders

The Order to Show Cause and the Government's Third Supplemental Prehearing Statement alleged that based on statistical analysis, between January 1, 2014 and April 30, 2018, the Respondent shipped 7,252 unusually large orders of oxycodone, totaling 12,594,100 dosage units and 4,948 unusually large orders of hydrocodone, totaling 22,042,800 dosage units. ALJ-1, at 5, para. 18; ALJ-52, at 19. The OSC also alleged that the Respondent shipped these orders and only reported three orders as being suspicious. ALJ-1, at 5, para. 20. In light of that high volume of unusually large orders for oxycodone and hydrocodone, and only reporting three orders as suspicious, the OSC also alleged that the Respondent failed to maintain effective controls against diversion of controlled substances into other than legitimate channels in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1), and 21 C.F.R. § 1301.71, and that the Respondent failed to report and identify suspicious orders to the DEA in violation of 21 C.F.R. § 1301.74(b). ALJ-1, at 5, para. 21. The Government also alleged that there were specific orders of unusual size that the Respondent filled for all of the exemplar pharmacies, except Hephzibah. ALJ-1, at 6-15; ALJ-52, at 20. With respect to the exemplar pharmacies, the Government alleged the Respondent filled the following numbers of unusually large orders of oxycodone and hydrocodone for the identified pharmacies:

[57] Both prior to the hearing and during the hearing, I advised the parties that they had the obligation to highlight the evidence each side was relying upon to prove their respective cases. *See* ALJ-49, at 2-3; Tr. 1095-96. Quoting from *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36487, 36503 n.25 (2007), I advised that "when a party intends to rely on evidence contained in a CD-ROM, it has the obligation to prepare a summary setting forth what the data contained therein show. . . . It is not the responsibility of the ALJ . . . to plumb the depths of such an exhibit to determine what the data show." ALJ-49, at 3. Although the Government did produce a Summary of Exhibits Produced in Native Format, it does not detail the numbers of orders or dosages as is contained in the OSC. ALJ-66, at 30-32. In addition, the number of shipments and dosages listed in the OSC and asserted as facts in the Government's Brief are not the same. Compare, for example, the paragraphs cited above with ALJ-90, Appendix A, at 27, paras. 96-97; at 31, paras. 108-09; at 39, paras. 130-31; at 45, paras. 145-46; at 55, paras. 170-71; at 57, paras. 179-80; and at 65, paras. 203-04. Furthermore, these numbers of shipments and numbers of dosage units as alleged in the OSC, and as asserted in the Government's Brief, were not addressed at the hearing or contained in the Government's Prehearing Statements. Without question, however, Government Exhibits 65 and 66 document that the Respondent shipped a very large number of shipments and an even larger number of dosage units of both oxycodone and hydrocodone to each of the exemplar pharmacies.

Pharmacy	Oxycodone	Hydrocodone
Wallace	1	6
Bordelon's	50	2
Folse	58	68
Pharmacy Specialties	10	15
Dave's	103	14
Wellness	119	3
Wilkinson	2	49

ALJ-52, at 20.

Statistical analysis is an appropriate method for identifying suspicious orders and the Tukey method is an appropriate method to conduct that analysis. FF 256. The Tukey method is a widely-recognized and commonly-used method of identifying statistical outliers. FF 215. It is also a useful tool for identifying outlier transactions that a distributor should investigate. *Id.* The Government applied the Tukey method to analyze the Respondent's sales of oxycodone and hydrocodone for the period between January 1, 2014 and April 30, 2018. FF 213, 224. In fact, the Government calculated the number of the Respondent's outlier orders two different ways while using the Tukey method. FF 213, 224, 231, 234, 241-43. First, the Government analyzed the Respondent's orders using a fixed-frame analysis. FF 224. Later, the Government analyzed the Respondent's orders using a look-back analysis. FF 234. Based upon the Tukey method, using a fixed-frame analysis, the Respondent filled 12,200 orders[58] between January 1, 2014 and April 30, 2018, that were significantly larger than normal. FF 215, 228, 231, 233. For the same time period, based upon the Tukey method, but using a look-back analysis, the Respondent filled 12,038 orders that were significantly larger than normal. FF 241-43. Between January 1, 2014 and April 30, 2018, however, the Respondent only submitted three suspicious order reports. FF 54, 199-201; Stip. 7. Furthermore, none of the three reports contained customer supplied information, as mentioned in the Respondent's SOP Manual. FF 198, 200, 202.

I accept the testimony of the Government statistical expert witness that he was using the Tukey method in this case to determine "a ballpark estimate" of the Respondent's outlier orders.

[58] Because this figure was calculated using data taken from the ARCOS system, the figure represents filled orders. FF 223.

While the Government's statistical expert referred to his analytical findings as "just math" (FF 236), he is a statistician, not an expert on the "requirements imposed on DEA registrants." Tr. 282. Thus, I also accept the expert testimony of the Group Supervisor, the Government's other expert, that these outliers are, in fact, suspicious orders that should have been reported. Tr. 294

I make this finding in spite of the testimony of the Respondent's expert in "statistical analysis related to controlled substance distribution," and in "pharmacy ordering and inventory management," Tr. 513-14, 520-21, who testified that the Government's analysis was unreliable. FF 245. As explained earlier in this opinion, I give greater weight to the testimony of the Government's statistician. Nevertheless, the Respondent's own evidence supports the conclusion that the Respondent received at least 10,000 suspicious orders between January 2014 and April 2018. Specifically, Respondent Exhibit 20 contains copies of the Respondent's suspicious order reports that the Respondent filed with the DEA between May 14, 2018 and July 29, 2018. RE-20. That exhibit contains 58 reports in which the Respondent informed the DEA of 3,915 suspicious orders. FF 297. The Respondent identified these suspicious orders using its new SOM system, which is based upon the Tukey method. FF 290. Although Respondent Exhibit 20 only covers a period of 11 weeks, Weinstein testified that he had run the Respondent's ordering data from early 2018 through his new system and the amounts were roughly consistent with what is contained in Respondent Exhibit 20. FF 297. In essence, he testified that the Respondent's new SOM system is catching about the same number of outliers on post-OSC data as it did on pre-OSC data. Tr. 666. Using a fixed-frame analysis the Government, however, identified only 564 suspicious orders in the first four months of 2018 (16 weeks). FF 231. That number pales when compared to the Respondent's own evidence showing almost 4,000 suspicious orders identified by the Respondent in 11 weeks between mid-May and the end of July 2018, a number similar to what the Respondent discovered when applying its new SOM system to the early months of 2018. Since Weinstein testified that the number of outliers the new SOM system is identifying on current data is similar to what it identified on pre-OSC data, and the Respondent's new SOM system identified 3,915 suspicious orders in 11 weeks on post-OSC orders, it is reasonable to conclude that over a period of 4 years and 4 months the number of suspicious orders would have been at least 10,000.

The Respondent also explained its lack of documentation, noting that keying errors made by a pharmacy were corrected by a phone call to the pharmacy, and then the order was shipped. FF 54. Such actions by the Respondent violated the reporting requirement of 21 C.F.R. § 1301.74(b). It does so for two reasons. First, as soon as the order was held for review, the order "met the criteria of a suspicious order," and the Respondent was required to report the order as suspicious. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55487 n.178. Second, "the suspicious order regulation requires the reporting of an order, regardless of whether the order is rejected entirely or edited by reducing the amount that is actually shipped." *Id.* at 55483. Thus, the Respondent's policy of editing an order and reducing the quantity of controlled substances its customer pharmacy had ordered essentially defeated the reporting requirement contained in the regulation. Further, the lack of documentation is evidence that the Respondent did not resolve these issues and that its due diligence was not effective.[59] *Masters Pharm., Inc.*, 861 F.3d at 218.

The Respondent's phone log also provides evidence of instances where the Respondent should have submitted a suspicious order report, but did not. Under the Respondent's old SOM system, the Respondent relied, in part, on input from its own employees who filled the orders. FF 280. Further, as noted above, as soon as the Respondent held the order for review, the order "met the criteria of a suspicious order." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55487 n.178. When the Respondent's employees raised concerns on March 7, 2016, and on December 13, 2017, about orders for controlled substances that Pharmacy Specialties had placed, there is no evidence in the Administrative Record that the Respondent suspended any shipments of controlled substances to Pharmacy Specialties or filed any suspicious order reports concerning that pharmacy. FF 142. There is evidence, however, that the Respondent continued to supply that pharmacy with oxycodone and hydrocodone. Stip. 14; RE-65-66. With respect to Hephzibah, the Respondent's phone log clearly indicates that the pharmacy was unwilling to cooperate with the Respondent's program, the Respondent closed the account.[60] FF 169. No suspicious order reports were filed concerning Hephzibah Pharmacy. Then on January 9, 2018, the Respondent's employees were concerned about orders placed by Wallace. GE-14, at 31. In fact, the Respondent stopped a shipment to Wallace due to that concern, and Wallace actually

[59] The Respondent's lack of documentation is another reason I accord lesser weight to the testimony of Weinstein. Weinstein testified that without context the Government's statistical results were not reliable. Tr. 541. Nevertheless, the Respondent's lack of documentation also prevents the ability to demonstrate context.

[60] Oddly, however, in an email to the DEA, the Respondent stated that it did not close the Hephzibah account due to suspicious activity. FF 169. I put greater weight on the content of the Respondent's contemporaneous phone log.

returned some hydrocodone that had already been shipped. *Id.* Again, there is no evidence that the Respondent reported these suspicious orders from Wallace.

The Respondent also informed DEA that as a result of its SOM system it had ceased supplying controlled substances to 42 pharmacies from 2014 through 2016. FF 281; RE-11, at 14. The Respondent's expert witness "in diversion," Tr. 851, acknowledged that if the Respondent had terminated those pharmacies based upon its SOM program, the Respondent should have filed suspicious order reports concerning those 42 pharmacies. Tr. 1015-16. There is no evidence that the Respondent did so.

Not only did the Respondent fail to report suspicious orders as required by 21 C.F.R. § 1301.74(b), the Respondent did so because it also failed to adequately "design and operate a system to disclose to the registrant suspicious orders of controlled substances." *Id.* The numbers themselves tell the story. Prior to April 2018, the Respondent's SOM program had identified less than 60 suspicious orders (3 suspicious order reports; 42 pharmacies with closed accounts; and possibly 15 orders identified in the Respondent's phone log). *Supra* note 17. Yet in the first 11 weeks of running its new SOM program, the Respondent identified almost 4,000 suspicious orders. In addition, even in those documented instances where the Respondent's employees identified concerns, FF 142, 169; *supra* note 17, there is no evidence that the Respondent filed a suspicious order report because of those concerns. Further, Irelan testified that the Respondent's old system could not hold orders[61] and there were limited places for notes. FF 277-78, 308. Thus, it is clear the Respondent's SOM system, as it existed before the issuance of the Order to Show Cause, was not effective. This finding is also consistent with the testimony of the Respondent's witnesses, Irelan and Milione. Tr. 720, 989, 1015-16.

Finally, the Government introduced evidence from the Government expert that supports the specific numbers of unusually large orders of oxycodone and hydrocodone that the Respondent shipped to seven of the exemplar pharmacies. FF 232. The evidence shows that between January 2014 and April 2018 the Respondent filled 500 unusually large orders for these two controlled substances for the seven exemplar pharmacies. *Id.* Further, the Government's evidence shows that the Respondent filled 156 of these orders between January 2017 and April

[61] Although Irelan testified that the old system could not hold orders, FF 278, the evidence establishes that some orders were held. For example, the Respondent reported that before filling orders where the ordering pharmacy mistakenly over-ordered, the Respondent would not fill the order, but rather it would call the pharmacy and "correct" the order before filling it. FF 54. In addition, the Respondent stopped shipment of an order to Wallace. GE-14, at 31 (first entry dated 1/9/18).

2018. FF 263. As previously discussed, I credit the testimony of the Government's statistical expert over that of the Respondent. I also credit the testimony of the Group Supervisor who testified that all of these unusually large orders were suspicious orders and should have been reported to the DEA. Tr. 294. Even if I accepted the calculations of the Respondent's statistical expert, I would still find that the Respondent filled 54 unusually large orders for oxycodone and hydrocodone for the seven exemplar pharmacies between January 2017 and April 2018. FF 263-64. Similarly, accepting the expert testimony of the Group Supervisor, I would find that these 54 orders should have been reported to the DEA.

The preponderance of the evidence establishes that the Respondent should have filed at least 10,000 suspicious order reports to the DEA between January 2014 and April 2018. At a minimum, the Respondent should have filed more than three suspicious order reports during that time period. The Respondent's own evidence supports this finding. First, Weinstein testified that his analysis of orders the Respondent filled identified about 50% of the outliers the Government had identified. FF 261. Second, another of the Respondent's experts, Milione, testified that the Respondent should have filed suspicious order reports at least in equal number to the number of pharmacies whose accounts the Respondent had closed based upon its old SOM system. FF 281. Third, the Respondent's phone log contained entries of approximately 15 suspicious orders. FF 209; *supra* note 17. It is also telling that during an 11 week period after the Respondent's new SOM system became operational, the Respondent reported well over 3,000 suspicious orders to the DEA, when compared to only 3 in the preceding four years. In addition, I note that when the Government applied the Tukey method, using the Respondent's look-back analysis, the Government found that the number of unusually large orders were roughly the same as when the fixed-frame analysis was used. FF 234, 242-43.

Based on the above evaluation of the evidence, when considered against the requirements to report suspicious orders, I find that the allegations contained in paragraph 21 of the Order to Show Cause that the Respondent failed to maintain effective controls against diversion of controlled substances into other than legitimate channels in violation of 21 U.S.C. §§ 823(b)(1), and 21 C.F.R. § 1301.71, and that the Respondent failed to report and identify suspicious orders to the DEA in violation of 21 C.F.R. § 1301.74(b), and the allegations contained in paragraphs 37, 46, 54, 65, 84, and 93, of the OSC, and ALJ-52, at 20, that the Respondent failed to report suspicious orders it filled for the seven exemplar pharmacies, also in violation of 21 U.S.C.

§ 823(b)(1), and 21 C.F.R. §§ 1301.71, and 1301.74(b), are **SUSTAINED.** These violations weigh in favor of revoking the Respondent's Certificates of Registration and denying any pending applications. The portions of the allegations in the Order to Show Cause in paragraphs 2, 19, 30, 36, 37, 45, 46, 53, 54, 64, 65, 74, 83, 84, 92, and 93, that refer to a specific number of dosage units of oxycodone or hydrocodone are **NOT SUSTAINED** because the Government either failed to introduce evidence in support of those allegations or it did not identify, either prior to or during the hearing, where in the Administrative Record the evidence supporting those specific numbers of dosage units can be found.[62]

DISCUSSION AND CONCLUSIONS OF LAW

As noted earlier, I have not sustained all of the Government's allegations. The allegations I have sustained, however, are enough to support my conclusion that the Respondent's continued registration is inconsistent with the public interest and my recommended sanction of revocation. Those sustained allegations concern the Respondent's failure to conduct effective due diligence of red flags of diversion with respect to eight exemplar pharmacies. Specifically, I have sustained the Government's allegations that the Respondent shipped controlled substances to the eight exemplar pharmacies for up to a period of about four years without resolving red flags raised in Pro-Compliance and Market Basket Reports. Those red flags included high percentages of cash payments; orders for controlled substances that far exceeded the national average; pharmacies that had a marked increase in the quantities of controlled substances they dispensed; pharmacies that dispensed 20 or more trinity drug cocktails; and pharmacies that filled prescriptions written by practitioners whose DEA registrations could not be verified. Although the Respondent conducted some due diligence that identified these red flags in the form of Pro-Compliance, Market Basket Reports, and a few phone calls, the Respondent's failure to resolve the red flags in those reports rendered its due diligence ineffective. Because the Respondent continued to supply controlled substances despite being aware of adverse information documented in due diligence reports, the Respondent's due diligence was ineffective at guarding against diversion, and therefore, the Respondent violated 21 C.F.R. § 1301.71(a) and 21 U.S.C. §§ 823(b) and (e).

[62] *Supra* note 57.

I have also sustained the Government's allegations concerning the Respondent's failure to report suspicious orders to DEA. Specifically, I have sustained the Government's allegation that the Respondent filed only three suspicious order reports to DEA over a period of about four years, when it should have filed thousands more. The Administrative Record does not conclusively establish the exact number of suspicious order reports that should have been filed during that period, but the preponderance of the evidence shows that the Respondent filled far more than only three orders that met the criteria of being suspicious.

The Government's expert identified (using the Respondent's own look-back method) approximately 12,000 outlier orders that were unusually large. The Government's expert also found roughly the same number of outliers using his own, fixed-frame method. And when the Respondent's expert applied his look-back method to outliers identified by the Government's expert over a period of only 16 months, the Respondent's own expert identified 1,680 outliers. FF 267. With respect to seven of the exemplar pharmacies, the Government's expert identified 500 outliers over a period of about four years. FF 232. Using his look-back approach, the Respondent's expert found 54 outliers for 16 of those months. FF 263-64. In addition, the Respondent claims that by applying its SOM policies that it ceased shipping orders to 42 pharmacies between 2014 and August 2016, yet the Respondent only submitted 3 suspicious order reports. FF 281, 338. While the Government has not proved the exact number of suspicious orders that should have been reported, the Government's evidence and the Respondent's analysis of that evidence, and the Respondent's new SOM system, show that it was at least 10,000. Significantly, these suspicious orders only include those of unusual size, not those of an unusual pattern or frequency. Simply put, three suspicious order reports barely scratched the surface. Thus, a preponderance of the evidence shows that during the relevant time period the Respondent failed to file suspicious order reports for thousands of orders that were of unusually large size in violation of 21 C.F.R. § 1301.74(b).

Folded into the allegation concerning failure to report suspicious orders is the allegation that the Respondent failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). With the Respondent failing to file approximately 10,000 suspicious order reports, it follows that the Respondent's system for identifying suspicious orders was ineffective. It also follows that the Respondent's suspicious order monitoring system was ineffective at "guard[ing] against . . . diversion of controlled

substances," in violation of 21 C.F.R. § 1301.71(a). Thus, I have also sustained the Government's allegation that the Respondent's pre-May 2018 SOM system violated these regulations.[63]

In sum, based on a preponderance of all the evidence, I have sustained the Government's allegations that the Respondent (1) shipped controlled substances without resolving red flags; (2) failed to file suspicious order reports; and (3) failed to operate a system that would identify suspicious orders. These sustained allegations support a finding that the Respondent harmed the public interest over a period of about four years and four months, and that its continued registration is therefore inconsistent with the public interest.

***Prima Facie* Showing and Balancing**

In its Brief, the Government set forth the five public interest factors to be considered when deciding whether a registration should be granted to, or revoked from, a distributor, citing both 21 U.S.C. §§ 823(b) and (e). ALJ-90, at 27 n.11. While the Government specifically noted that it was not making any allegations against the Respondent concerning Factors Three or Five, I note that it also made no argument in its Brief concerning Factor Two. *Id.* at 28 n.12. In arguing its case, the Government combines Factors One and Four, but does not conduct any specific analysis concerning Factor Four. *Id.* at 28-44. Rather, the Government concludes that the "magnitude and nature of Respondent's violations weigh heavily in favor of revocation." *Id.* at 44. The Respondent also cites the public interest factors, and conducts an analysis of all five factors, concluding that each weighs in favor of the Respondent. ALJ-89, at 110-20, paras. 289-312.

These public interest factors are considered separately. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55472; *Ajay S. Ahuja, M.D.*, 84 Fed. Reg. 5479, 5488 (2019). Each factor is weighed on a case-by-case basis. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55473; *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive.

[63] Even if the Respondent had the option to investigate the unusually large orders and determine they were not suspicious, an option I find to be inconsistent with the express language of 21 C.F.R. § 1301.74(b), in retrospect that option is not available to the Respondent. It is not available because the Respondent kept no records documenting the resolution of the question of why its customer pharmacies had submitted these unusually large orders. Without question, the pharmacies could have supplied numerous explanations to provide a legitimate reason for the large orders, which would have allowed the Respondent to ship the orders. Without documentation of those reasons, however, the orders remain suspicious, and serve as proof of the Respondent's lack of due diligence, its failure to design and operate a system to identify suspicious orders, and its failure to maintain *effective* controls against diversion.

David H. Gillis, M.D., 58 Fed. Reg. 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55473; *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005). Further, there is no requirement to consider a factor in any given level of detail. *Trawick v. DEA*, 861 F.2d 72, 76-77 (4th Cir. 1988). When deciding whether registration is in the public interest, the totality of the circumstances must be considered. *See generally Joseph Gaudio, M.D.*, 74 Fed. Reg. 10083, 10094-95 (2009). Given the nature of this case, however, I have found it appropriate to focus only on Factor One, which weighs heavily in favor of revocation of the Respondent's Certificates of Registration.

After the Government presents a *prima facie* case for sanction, the Respondent has the burden of production "to show why its continued registration would not be inconsistent with the public interest." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55473; *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36498. DEA precedent has established two avenues for rebutting a *prima facie* showing for sanction: (1) accepting responsibility, and (2) remediation. *Ajay S. Ahuja, M.D.*, 84 Fed. Reg. at 5497. In addition, when assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of the offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, M.D.*, 78 Fed. Reg. 38363, 38385 (2013).

To rebut the Government's *prima facie* case, the Respondent "'must accept responsibility for its actions and demonstrate that it will not engage in future misconduct.'" *Masters Pharm., Inc.*, 80 Fed. Reg. at 55501 (quoting *Medicine Shoppe*, 73 Fed. Reg. at 387). Acceptance of responsibility must be unequivocal in order to successfully demonstrate that a respondent can be trusted with a DEA registration. *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74800, 74801 (2015). Where a respondent's testimony is "equivocal and unpersuasive" concerning acceptance of responsibility, it is appropriate to conclude that the respondent has not produced sufficient evidence to demonstrate that he can be trusted with DEA registration. *Perry Cty. Food & Drug*, 80 Fed. Reg. 70084, 70090 (2015). In addition, "candor is an important and typically dispositive consideration" in determining whether a registrant has accepted responsibility for its actions. *Jeri Hassman, M.D.*, 75 Fed. Reg. 8194, 8236 (2010).

The Respondent may accept responsibility by providing evidence of its remorse, its efforts at rehabilitation, and its recognition of the severity of its misconduct. *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15227, 15228 (2003). In accepting responsibility a respondent is required to acknowledge all acts of misconduct that are proven by the Administrative Record. *See Mark*

William Andrew Holder, M.D., 80 Fed. Reg. 71617, 71628 n.25 (2015) (collecting cases). In other words, a registrant "is not required to accept responsibility for misconduct which has not been proved on the record." *David Ruben, M.D.*, 78 Fed. Reg. at 38386 n.49; *Mark G. Medinnus, D.D.S.*, 78 Fed. Reg. 62683, 62684 (2013) (citing *Jeffrey P. Gunderson, M.D.*, 61 Fed. Reg. 26208, 26211 (1996)).

For an acceptance of responsibility to be effective, a respondent must show "true remorse" for wrongful conduct. *Michael S. Moore, M.D.*, 76 Fed. Reg. 45867, 45877 (2011). The respondent's expression of remorse and acknowledgment of wrongdoing are relevant considerations in the acceptance of responsibility inquiry. *Wesley G. Harline, M.D.*, 65 Fed. Reg. 5665, 5671 (2000). Simply acknowledging, however, that the registrant's practices need improvement is not an effective acceptance of responsibility. *Darryl J. Mohr, M.D.*, 77 Fed. Reg. 34998, 35019 (2012). Relatedly, a respondent does not accept responsibility for its actions simply by taking remedial measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195*, 77 Fed. Reg. 62316, 62346 (2012). The DEA can require an applicant to acknowledge the full extent of his proven misconduct before granting (or continuing) registration; thus, even if the applicant or registrant undertook remedial measures, refusal to acknowledge the *full scope of misconduct* is a risk to the public interest. *Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8250-51 (2016). The DEA's reliance on acceptance of responsibility has been sustained on review. *MacKay v. DEA*, 664 F.3d 808, 819-20 (10th Cir. 2011).

The purpose of requiring registrants to present evidence of remediation or corrective measures is to assure the DEA that similar misconduct will not be repeated. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. 79188, 79217 (2016). An effective acceptance of responsibility is necessary in order for remedial evidence to be a relevant consideration. *Ajay S. Ahuja, M.D.*, 84 Fed. Reg. at 5498 n.33; *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79202; *The Medicine Shoppe*, 79 Fed. Reg. 59504, 59510 (2014). Thus, where a respondent fails to accept responsibility, "there is no need to address whether the remedial measures [respondent] claims to have instituted are adequate to protect the public interest." *Id.* (citing *Medicine Shoppe—Jonesborough*, 73 Fed. Reg. 364, 387 (2008)).

"[E]ven where a registrant accepts responsibility and demonstrates that he has undertaken remedial measures, in determining the appropriate sanction, the [DEA] can still consider the

need to deter both the particular registrant, as well as others, from engaging in similar acts." *David A. Ruben, M.D.*, 78 Fed. Reg. at 38385. Acceptance of responsibility and remedial measures are, therefore, balanced against the "egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others." *David A. Ruben, M.D.*, 78 Fed. Reg. at 38364. Thus, in addition to weighing the respondent's acceptance of responsibility and evidence of remediation, the DEA considers the egregiousness of the respondent's misconduct and the need for deterrence in crafting the appropriate sanction.

Although these proceedings are remedial in nature, rather than punitive, the DEA, and other administrative agencies, have consistently considered deterrence in determining the appropriate sanction. *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23848, 23853 (2007); *see also McCarthy v. SEC*, 406 F.3d 179, 188-89 (2d Cir. 2005) (affirming SEC's use of "deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions"). Thus, "even when a proceeding serves a remedial purpose, an administrative agency can properly consider the need to deter others from engaging in similar acts." *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36504. "Consideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest" and by "the broad grant of authority" delegated to DEA in the Controlled Substances Act. *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36504; *see also Butz v. Glover Livestock Comm'n Co., Inc.*, 411 U.S. 182, 186-87 (1973) (concluding that the Department of Agriculture's sanction authority achieved statutory objectives by deterring potential violators).

The DEA considers specific and general deterrence. Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Glick*, 80 Fed. Reg. at 74810. General deterrence concerns DEA's responsibility to deter conduct similar to the proven allegations against the respondent for the protection of the public at large. *Id.*

"[W]hile proceedings under 21 U.S.C. §§ 823 and 824 are remedial in nature, there are cases in which, notwithstanding a finding that a registrant has credibly accepted responsibility, the misconduct is so egregious and extensive that the protection of the public interest nonetheless warrants the revocation of a registration or the denial of an application." *William J. O'Brien, III,*

D.O., 82 Fed. Reg. 46527, 46527 (2017) (quoting *Hatem Ataya, M.D.*, 81 Fed. Reg. 8221, 8244 (2016)) (citation omitted).

Acceptance of Responsibility

At the hearing, Government counsel asked Mr. Irelan whether he brought with him "any notarized power of attorney or other authority showing that you have proof to speak for the company?" Tr. 790. Mr. Irelan said he did not. *Id.* Government counsel then pointed to 21 C.F.R. § 1316.50, arguing that it "deals with attorney representatives but also, I believe, deals with corporate representatives." Tr. 791. Section 1316.50, titled "Appearance; representation; authorization," provides that a respondent may appear in DEA administrative proceedings "in person or by a representative." 21 C.F.R. § 1316.50. It then provides that "[a] representative must either be an employee of the [respondent] or an attorney at law." *Id.* It then states that "[a]ny representative may be required . . . to present a notarized power of attorney showing his authority to act in such representative capacity and/or an affidavit or certificate of admission to practice." *Id.*

In its Brief, the Government continues to rely upon 21 C.F.R. § 1316.50. ALJ-90, at 46. The Government, however, acknowledges that it "is not aware of any Agency decisions specifically addressing who can accept responsibility on behalf of a corporate (or other non-individual) registrant." *Id.* In general support of its position, the Government cites to *OTC Distribution Co.*, 68 Fed. Reg. 70538 (2003). *Id.* Without citation to any primary authority the Respondent argues that 21 C.F.R. § 1316.50 "is intended to notify litigants of who is permitted to conduct litigation on behalf of a respondent," and it "simply does not address the capacity of a corporate representative to accept responsibility." ALJ-89, at 65-66, para. 196. In its argument that Mr. Irelan was qualified to accept responsibility on behalf of the Respondent, the Respondent relies on *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316 (2012). ALJ-89, at 63-64, paras. 191-93.

The DEA cases tend to support the Respondent's argument that 21 C.F.R. § 1316.50 addresses counsel issues. Section 1316.50 is cited almost exclusively with respect to a respondent's right to retain legal counsel. *Kenneth N. Woliner, M.D.*, 83 Fed. Reg. 7223, 7223 (2018); *Thomas Horiagon, M.D.*, 81 Fed. Reg. 79051, 79051 (2016); *Jana Marjenhoff, D.O.*, 80 Fed. Reg. 29067, 29069 n.4 (2015); *Stephanie A. Tarapchak, M.D.*, 77 Fed. Reg. 73677, 73677 (2012); *Linda Sue Cheek, M.D.*, 76 Fed. Reg. 66972, 66975 (2011); *Shawn M. Gallegos, D.D.S.*,

76 Fed. Reg. 66986, 66987 n.5 (2011); *Richard A. Herbert, M.D.*, 76 Fed. Reg. 53942, 53942 (2011); *Sheryl Lavender, D.O.*, 76 Fed. Reg. 48897, 48897 (2011); *Michael W. Dietz, D.D.S.*, 66 Fed. Reg. 52937, 52937 (2001); *William Peterson, M.D.*, 66 Fed. Reg. 52943, 52943 (2001). A review of the DEA's final orders did not reveal any case in which the Administrator held that corporate respondents must abide by 21 C.F.R. § 1316.50 when designating witnesses to testify on the corporation's behalf.

I note, however, that the case that comes closest to supporting the Government is the case it cited, *OTC Distribution Co.*, 68 Fed. Reg. 70538 (2003), where the president-owner of a corporate respondent filed a power of attorney pursuant to Section 1316.50 authorizing an individual to serve as the respondent's corporate representative in the DEA proceeding. *Id.* at 70539. That individual testified at the hearing on the respondent's behalf, but the Administrator's decision did not say that a power of attorney was required in order for the witness to testify or that corporate respondents must comply with Section 1316.50 when selecting representatives to testify. *Id.* In fact, the decision adds no commentary whatsoever on how Section 1316.50 applied, or was even relevant, to that situation. *Id.* The Administrator's lone reference to Section 1316.50 seems more of a factual or procedural note rather than a statement of law concerning that section. Thus, although the reference to Section 1316.50 in *OTC Distribution* comes closer than any other DEA case in supporting the Government's position, it does not provide any authority for the proposition that the Respondent was required to submit a power of attorney to testify as the company's corporate representative.

This does not mean, however, that the Respondent is in the clear, especially when it comes to Mr. Irelan's authority to accept responsibility on the company's behalf. The Respondent itself cannot accept responsibility because the Respondent is a family-owned business. Acceptance of responsibility, therefore, must come from an individual or individuals. Where the registrant is not an individual, but rather a company, the DEA has long held that the misconduct of the company's owners, directors, or managers are properly considered in determining whether to revoke the company's registration. *Chip RX, L.L.C., d/b/a City Ctr. Pharmacy*, 82 Fed. Reg. 51433, 51438 (2017) (citing *G & O Pharmacy of Paducah*, 68 Fed. Reg. 43752, 43753 (2003)). Similarly, the DEA's position in cases where the registrant was not a person is that the company's "principals" need to take responsibility. *Sun & Lake Pharmacy,*

Inc., 76 Fed. Reg. 24523, 24533 (2011); *R & M Sales Co., Inc.*, 75 Fed. Reg. 78734, 78744 (2010).

Given DEA's position that it will examine the misconduct of owners, directors, or managers when a registrant is a company, and that principals need to take responsibility for misconduct, the Respondent's assertion that Mr. Irelan is "better positioned than anyone at Respondent to discuss Respondent's past failings" is disingenuous and reflects a lack of candor on the Respondent's part. ALJ-89, at 63, para. 190. Although Mr. Irelan was a manager with the Respondent prior to the issuance of the OSC, he was not an owner of the company or a director of the company. FF 343, 353; Tr. 689. Furthermore, prior to the issuance of the OSC, Mr. Irelan's managerial position had nothing to do with the Respondent's SOM program or its due diligence efforts. FF 341-42. Finally, his testimony concerning the Respondent's SOM program and its due diligence efforts was based upon his review of the Respondent's records, not first-hand knowledge. FF 356.

As noted earlier, the Respondent relies on *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316 (2012), in its argument that Mr. Irelan could accept responsibility for the Respondent's misconduct. ALJ-89, at 63-64, paras. 191-93. I find that reliance to be misplaced. In support of its argument that in *Holiday CVS, L.L.C.*, "[t]he Administrator did not dictate which corporate officer can or cannot accept responsibility and did not require that the individuals who committed the misconduct must have accepted responsibility themselves," the Respondent quoted the following from that decision: "the fact that CVS is a large corporation provides no reason to excuse it from explicitly acknowledging the misconduct of Respondents and their pharmacists." *Id.* at 64, para. 193. As the Respondent has pointed out repeatedly throughout this case, context is important. Immediately preceding the language quoted above from *Holiday CVS*, the decision discussed an exception that had been filed in that case to the decision of the Administrative Law Judge. The exception asserted that:

> other DEA revocation cases bear a crucial distinction from this case: in virtually all of those cases, the individual doctor or independent pharmacy owner/ pharmacist was both the one accused of wrongdoing and the registrant. As such, these individuals were in a position to apologize for their own misconduct or that of the retail pharmacy they owned or operated.

Holiday CVS, L.L.C., 77 Fed. Reg. at 62323. In direct response to that exception, the Administrator of DEA wrote:

> Be that as it may, the Agency's rule is clear and the fact that CVS is a large corporation provides no reason to excuse it from explicitly acknowledging the misconduct of Respondents and their pharmacists. Therefore, I decline to create one rule for chain pharmacies and another rule for closely held or sole-proprietor owned pharmacies. Because Respondents have failed to satisfy this requirement, the ALJ properly held that they have not accepted responsibility for their misconduct.

Id. (emphasis added). In context, it is clear that the Administrator was not creating a different rule for chain pharmacies, rather the Administrator anticipated that acceptance of responsibility should always come from individuals who were "in a position to apologize for their *own* misconduct or that of the [company] they *owned or operated*."[64] *Id.* (emphasis added). This language is consistent with earlier decisions from the DEA that where the registrant is a company, the principals are required to take responsibility for their misconduct. *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. at 24533; *R & M Sales Co., Inc.*, 75 Fed. Reg. at 78744. Mr. Irelan, however, engaged in none of the alleged, and proven, misconduct, and at the time of the misconduct he was not a principal.

For all of the above reasons, I find that Mr. Irelan lacked standing to accept responsibility for the Respondent. Even if Mr. Irelan was a proper individual to accept responsibility on the Respondent's behalf, however, there are several factual considerations that cut against the weight of his acceptance of responsibility, and thus whether the offered acceptance of responsibility was unequivocal.

First, although Mr. Irelan currently appears to enjoy nearly total control over the Respondent's compliance program, he does not truly have the final say. For example, Mr. Irelan testified that he is not required to obtain approval from anyone regarding the Respondent's budget for its compliance team; no member of the Dickson family has complained to him about the expense of operating the Respondent's compliance team; he is not required to discuss with any member of the Respondent's management about decisions he makes regarding suspicious order monitoring; no one at the Respondent has suggested to him that he cannot take actions that he wants to take regarding compliance; no one has ever told him he cannot hire or terminate a

[64] In *Holiday CVS*, the Administrator agreed with the ALJ that CVS did not accept responsibility for the actions underlying the Government's *prima facie* case. *Holiday CVS, L.L.C.*, 77 Fed. Reg. at 62323. The Administrator noted that during the testimony of the Vice President of Pharmacy Operations for CVS, the Vice President never acknowledged that CVS had engaged in any misconduct. *Id.* Further, it is not clear from the decision whether the Vice President held that position with CVS at the time of the alleged misconduct.

member of the Respondent's compliance team; and that he is the final decision maker regarding staffing the Respondent's compliance team. FF 346-50.

This testimony suggests that after the OSC Mr. Irelan has been the primary decision maker regarding how the Respondent spends money on compliance; who works for the Respondent's compliance team; and how the compliance program is run. Apparently the Respondent trusts Mr. Irelan with these duties since he does not have to obtain approval regarding the compliance program's budget and does not have to discuss decisions regarding suspicious order monitoring with the Respondent's management. FF 346, 348.

Yet, Mr. Irelan also testified that Paul Dickson, Sr., could terminate the Respondent's employment of Guidepost, AGI, and Mr. Irelan with virtually no notice. FF 353-54. In fact, the Government asked Mr. Irelan at the hearing, "if Mr. Dickson, Sr., the president, wanted to fire you tomorrow, could he?", and Mr. Irelan responded, "Yes." Tr. 804. The Government followed by asking whether Mr. Dickson, Sr., could fire Guidepost, AGI, and Cadwalader "tomorrow," and Mr. Irelan responded that Mr. Dickson could fire all of them. Tr. 805. While employment decisions are the Respondent's prerogative and maintaining Mr. Irelan's employment is certainly not required in order to be compliant, the fact that individuals at the Respondent (who did not testify at the hearing) could abruptly terminate the company's Director of Corporate Compliance as soon as the day after he testified gives me pause.

For the same reasons it gives me pause that the same individuals at the Respondent (who, again, did not testify at the hearing) could also terminate the company's relationship with Guidepost and AGI. When Government counsel asked Mr. Irelan who would have the final decision regarding how long to employ Guidepost and AGI, Mr. Irelan initially answered, "At this point, I would," but then explained that the decision would have to go up the chain of command to the Vice President of Operations, then to Paul Dickson, Sr., then to the company's Board of Directors. Tr. 803-04. If Mr. Irelan believed, as Director of Corporate Compliance, that the Respondent needed to continue its relationship with these firms in order to remain compliant, that decision, ultimately, would not be his to make.

Because Mr. Irelan and these firms could be fired so easily by the company's President, then Mr. Irelan's authority is still subject to higher authorities within the company who may not always sign-off on Mr. Irelan's work, even though they have done so thus far. Therefore, a question remains whether the Respondent might not return to its old ways if those responsible

for the Respondent's reform efforts (Mr. Irelan, AGI, and Guidepost) can be abruptly terminated by individuals who did not appear in these proceedings. All we have is the word of one employee who could be fired "tomorrow." Tr. 804. While these considerations do not completely discredit or undermine Mr. Irelan's acceptance of responsibility, they do diminish its weight and power to persuade. These considerations also call into question the extent to which Mr. Irelan speaks for the company. These considerations impact the determination of whether the Respondent's acceptance of responsibility was unequivocal.

Second, as noted earlier, "candor is an important and typically dispositive consideration" in determining whether a registrant has accepted responsibility for its actions. *Jeri Hassman, M.D.*, 75 Fed. Reg. at 8236. The issue is not simply one of Mr. Irelan's candor, but also the candor of the Respondent. Here, the Respondent elected to send its newly-appointed compliance officer to accept responsibility for misconduct of which he was not involved. In fact, he had no first-hand knowledge of any of the misconduct. His testimony about acceptance of responsibility was based on his review of company records, which the Respondent did not produce as evidence.[65] While the Respondent suggests that Mr. Irelan was the best witness the Respondent had to accept responsibility, the Respondent fails to explain why Paul Dickson, Sr., Jacob Dickson, or Clara Guin, would not have been in a better position to accept responsibility for the misconduct that occurred on their watch. *See Holiday CVS, L.L.C.*, 77 Fed. Reg. at 62323 (stating that acceptance of responsibility should come from an individual who can apologize for his or her "own misconduct" or for the company he or she "owned or operated"). Furthermore, the Respondent is a family-owned business, and Paul Dickson was the President during the relevant period of time. In this family environment, had Mr. Dickson significantly offended another family member, how sincere would that family member find Mr. Dickson's apology to be if the apology was delivered by someone else? In essence, that is what happened here—the apology was offered by someone not responsible for the wrongdoing. It is worth repeating, candor is an important and typically dispositive consideration in determining whether a registrant has accepted responsibility for its actions. When a corporate or family-owned registrant decides

[65] In its Brief, the Respondent stated that it was unfair for the Government to have offered only portions of documents, citing the "rule of completeness." ALJ-89, at 92, para. 255. I reject the Respondent's argument for several reasons. First, the Respondent did not raise the rule of completeness during the hearing. Second, the Respondent was on notice for many months of the documents the Government intended to offer. Third, the Respondent failed to identify additional documents it wished to offer prior to the hearing that would have made the Government's exhibits "whole." Fourth, the Respondent called no witnesses to identify such evidence, such as the possible attachments to Government Exhibit 9.

to send a representative who has no first-hand knowledge of, and who was not responsible for, proven violations of the CSA and its implementing regulations, to accept responsibility on behalf of the registrant, while principals who still work for the registrant and who were responsible, at least in part, for the proven misconduct could have testified, that decision calls into question the registrant's candor in accepting responsibility. This, in turn, impacts the determination of whether the Respondent's acceptance of responsibility was unequivocal.

Third, a respondent must accept responsibility for all the misconduct that the Government proved. *Lon Alexander, M.D.*, 82 Fed. Reg. 49704, 49730 n.54 (2017). Furthermore, a registrant is required to acknowledge the full extent of its misconduct and the failure to acknowledge the scope of one's misconduct is a risk to the public interest. *Id.*; *Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8250-51 (2016). While there was no reason for Mr. Irelan to accept responsibility for the Respondent failing to conduct "any" additional due diligence because the Government did not prove that repeated allegation, his failure to accept the scope of the Respondent's misconduct renders his attempted acceptance of misconduct to be less than unequivocal. For example, the Government proved that the Respondent failed to report thousands of suspicious orders. Yet, the Respondent's apparent position is that the Government did not prove that any of the orders for hydrocodone or oxycodone that the Respondent filled were suspicious. ALJ-89, at 34-42, paras. 98-118. The scope of the Respondent's misconduct is that it shipped suspicious orders without reporting them to the DEA. Nowhere in Mr. Irelan's testimony is it clear that he accepted responsibility for such misconduct. In fact, to have done so would have been inconsistent with the Respondent's presentation of Mr. Weinstein's testimony that the Government's statistical analysis was unreliable and that the Government did not prove that outliers identified by the analysis were in fact suspicious orders. Furthermore, Mr. Irelan testified that he was not in a position to accept responsibility for, or he could not speak to, some of the allegations contained in the OSC. FF 368-69.

In addition, Mr. Irelan's attempted acceptance of responsibility for filling orders to the exemplar pharmacies without resolving the numerous red flags identified in the numerous Pro-Compliance Reports, seemingly was limited to the Respondent's failure to apply due diligence. Tr. 720-21. Nevertheless, the Government clearly proved that the Respondent's due diligence efforts were inadequate and ineffective, not simply that the Respondent failed to apply its due diligence. Furthermore, based upon the lack of documentation of due diligence efforts, it is clear

that little was performed. Clearly, Mr. Irelan did not acknowledge the *scope* of the Respondent's misconduct. *Arvinder Singh, M.D.*, 81 Fed. Reg. at 8250-51. This impacts the determination of whether the Respondent's acceptance of responsibility was unequivocal.

Whether something is unequivocal requires consideration of several factors. Among those factors are questions of whether the witness: has the authority to speak for the registrant; demonstrates knowledge of the misconduct, the scope of the misconduct, and what the law requires; is the best witness the registrant could produce to accept responsibility; was responsible for some or all of the misconduct; and accepts responsibility for the proven allegations and the scope of the misconduct. In addition, the Respondent's candor in its acceptance of responsibility is another factor. Given those considerations, and the analysis set forth above, I find that the Respondent's acceptance of responsibility was equivocal.

Remediation

Without question, the remedial actions the Respondent has taken since the issuance of the OSC have been impressive. FF 284-88, 291-301, 303, 307-08, 310-11, 322-330. "The Agency has recognized[, however,] that a cessation of illegal behavior only when 'DEA comes knocking at one's door,' can be afforded a diminished weight borne of its own opportunistic timing." *Mireille Lalanne, M.D.*, 78 Fed. Reg. 47750, 47777 (2013) (quoting *Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. 48887, 48897 (2011)). Although a respondent's post-OSC remediation may be impressive and is relevant in determining whether respondent rebutted the Government's case, the DEA will not ignore the fact that the respondent decided to become compliant with regulatory requirements only *after* the initiation of administrative enforcement proceedings. *Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. at 48897. In other words, it should not take the issuance of an OSC to motivate a registrant to take its regulatory obligations seriously. But that is what appears to have happened in this case.

It should come as no surprise that the Respondent's "after-the-fact good works" merit "a skeptical eye." *Swinton v. Potomac Corp.*, 270 F.3d 794, 815 (9th Cir. 2001). Considering that the Respondent has been in operation since 1841, it is not the new kid on the block in terms of distributing pharmaceuticals; it has *178 years of experience* working in the industry. *See, e.g.*, GE-6, at 1; Tr. 694. Thus, it is hard to fathom why it took such an experienced company 177 years, receipt of several DEA letters explaining the requirement to report suspicious orders,

personal meetings with DEA representatives reinforcing those requirements, and the receipt of an OSC/ISO to realize that it needed a better SOM system and improved due diligence practices.

In *Southwood Pharmaceuticals, Inc.*, the Deputy Administrator gave no weight to the respondent's "stroke-of-midnight decision" to cease supplying suspect pharmacies with controlled substances and to employ a compliance officer. 72 Fed. Reg. at 36503. The evidence of record here suggests that the Respondent's rapid enhancement of its SOM system and due diligence were "stroke-of-midnight decision[s]" spurred by the OSC/ISO. *Id.* Furthermore, where a registrant has not unequivocally accepted responsibility, as in the case here, remedial measures are not relevant. *Ajay S. Ahuja, M.D.*, 84 Fed. Reg. at 5498 n.33. Accordingly, I give no weight to the Respondent's remediation efforts.

Deterrence

I find that general deterrence weighs in favor of recommending revocation.[66] Given the egregiousness of the Respondent's misconduct, recommending anything less than revocation in this case would suggest that no matter how badly a registrant violates the CSA, the registrant could keep its COR so long as it tenders a semi-unequivocal acceptance of responsibility and introduces evidence that it will follow the law in the future. *David A. Ruben, M.D.*, 78 Fed. Reg. at 38387. The Administrator's reasoning in *David A. Ruben, M.D.*, is worth quoting in full:

> In short, [continuing a practitioner's COR with conditions, rather than imposing a revocation,] would send the message that a practitioner can unlawfully distribute controlled substances until he/she gets caught, and as long as he/she then acknowledges wrongdoing and puts on evidence that he/she has reformed, he/she will get a slap on the wrist. This is the entirely wrong message to send to those practitioners who contemplate using their prescribing authority for illicit purposes.

Id. The same is true here. Continuing the Respondent's COR or issuing a suspension—in other words, anything less than revocation—would communicate to DEA registrants that despite their transgressions, no matter how egregious, they will get a mere "slap on the wrist" and a second chance so long as they acknowledge their sins and vow to sin no more. *See Hatem Ataya, M.D.*, 81 Fed. Reg. at 8244 (stating that even if Administrator credited respondent's acceptance of responsibility and considered his remedial evidence, he "would nonetheless find that his conduct was so egregious that the protection of the public interest warrants the revocation of his

[66] I would make this same finding, even if I had found that the Respondent had accepted responsibility, and even considering the Respondent's impressive remedial measures.

registrations and the denial of his pending applications"). If it were that easy to escape sanction, no registrant would take its responsibilities seriously until it was caught, because it would only need to apologize and promise to reform to get one more bite at the apple. Registrants do not merit a second bite when the first bite was as huge as the bite the Respondent took, one resulting in thousands of unreported suspicious orders being shipped and countless dosages of addictive and potentially lethal controlled substances flooding the market for many years.

The regulated community must know, however, that violating the CSA will result in "serious consequences." *Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7336 (2018). Acceptance of responsibility and evidence of remediation are not get-out-of-jail-free cards that erase the harm caused by years of cavalier disregard for the duties of a DEA registrant. Allowing the Respondent to keep its registration would tell distributors that it is acceptable to take a relaxed approach to DEA regulations until they are caught at which point they only need to throw millions of dollars at the problem to make DEA go away. As Milione stated, the Respondent has "spared no expense" in becoming compliant. FF 288. But this was expense that should have been spent *before* DEA began investigating, not after the Administration conducted a full investigation and decided to issue an OSC.

Relationship between the Shreveport and Jefferson Certificates of Registration

The Respondent currently possesses two Certificates of Registration, one for its location in Shreveport, Louisiana, and one for its location in Jefferson, Louisiana. Stips. 1-2. The Respondent argues that there is not a single allegation contained in the OSC concerning the Jefferson location, and that no testimony was presented concerning that location. ALJ-89, at 11, para. 27. The Respondent also argues that "[t]here was not a scintilla of evidence or testimony at the hearing regarding the [Jefferson] registration." *Id.* at 2-3. The Respondent is technically correct. The OSC does not allege that violations occurred at the Jefferson location. ALJ-1. For that matter, however, the OSC also does not allege that the violations occurred at the Shreveport location. *Id.* In addition, there is no testimony or evidence specifying that violations occurred at the Jefferson location, or, for that matter, that the violations occurred at the Shreveport location, though Respondent Exhibit 1 does indicate that the Respondent has one distribution center, which is located in Shreveport, from which distributions are made. RE-1, at 15, 17. Rather, the OSC simply alleged that the Respondent committed the violations. ALJ-1. Furthermore, the

Jefferson location is owned by the Respondent, and the company uses it to "secure controlled substances . . . in transit." RE-1, at 16.

The DEA treats "two separately organized business entities as one integrated enterprise . . . based on the overlap of ownership, management, and operations of the two entities." *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79222 (citing *MB Wholesale, Inc.*, 72 Fed. Reg. 71956, 71958 (2007)). In this case, the evidence clearly established that there is an overlap in ownership, management, and operations.

In terms of ownership, it is clear from the record that the Respondent owns both the Shreveport and Jefferson locations. RE-1, at 15-16. As far as management and operations, the Respondent is a "family-owned" business, and Paul Dickson, Sr., is the President of the business. RE-1, at 13; Tr. 694, 803, 835. In addition, Paul Dickson, Jr., is the company's Vice President of Operations, Tr. 804, and Jacob Dickson had been the company's compliance officer/SOM Manager/Vice President of Marketing. Tr. 67, 401-02, 452, 794, 809; GE-9, at 5; GE-72, at 2.

Because of the obvious commonality of ownership, management, and operations, it is abundantly clear that if the Respondent's Shreveport COR was revoked, but the Respondent was allowed to keep its Jefferson COR, the Respondent could continue distributing out of its Jefferson location. Accordingly, due to that commonality, it is appropriate to treat the Respondent's two locations and two CORs as one integrated enterprise.

RECOMMENDATION

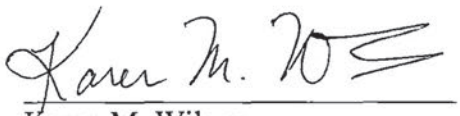
The Government established that the Respondent's continued registration is inconsistent with the public interest. The Government established a *prima facie* case for revocation by proving that the Respondent (1) shipped large quantities of controlled substances without resolving red flags; (2) failed to file thousands of required suspicious order reports; and (3) failed to operate a system that would identify suspicious orders. Because the Respondent's failure to comply with the requirements of the Controlled Substances Act and DEA regulations implementing that Act was so egregious, and because the DEA has the responsibility to consider general deterrence, the most severe sanction is appropriate in this case. Accordingly, I **RECOMMEND** that the Respondent's DEA COR Numbers RM0314790 and RM0335732 be **REVOKED,** and that any application for renewal or modification of these registrations be **DENIED.**

Dated: August 29, 2019

Charles Wm. Dorman
U.S. Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on August 29, 2019, caused a copy of the foregoing to be delivered to the following recipients: (1) Counsel for the Government, Paul A. Dean, Esq., and John E. Beerbower, Esq., Office of Chief Counsel, Drug Enforcement Administration, via email to the DEA Government Mailbox at: dea.registration.litigation@usdoj.gov; and to (2) Counsel for Respondent, Jodi L. Avergun, Esq., Keith M. Gerver, Esq., and Joshua P. Arnold, Esq., Cadwalader, Wickersham & Taft, LLP, via email to: jodi.avergun@cwt.com, keith.gerver@cwt.com, and joshua.arnold@cwt.com.



Karen M. Wilson
Secretary
Office of Administrative Law Judges

Exhibit 6

MORRIS & DICKSON CO., LLC,

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

DECLARATION OF JIM WALDEN

Jim Walden, pursuant to 28 U.S.C. §1746, hereby declares under penalty of perjury as follows:

1. I, along with my firm, Walden Macht & Haran LLP ("Walden Macht & Haran"), represent Morris & Dickson Co., LLC ("Morris & Dickson").

2. I offer this declaration to provide background on Morris & Dickson's settlement negotiations with the Drug Enforcement Administration ("DEA") in connection with its administrative matter, Docket No. 18-31.

3. Morris & Dickson was initially represented in the administrative matter by Cadwalader, Wickersham & Taft, LLP. Walden Macht & Haran was substituted as counsel in December 2021. From my review of memoranda in our voluminous client file, I understand that Morris & Dickson has been trying to resolve this matter

through settlement since August 2018. Between August 2018 through November 2019, Morris & Dickson offered DEA several proposals, although no settlement was reached.

4. Shortly after Walden Macht & Haran became counsel for Morris & Dickson, in January 2022, M&D met with DEA at their offices in Arlington, Virginia. At that time, nearly three years had elapsed without meaningful direct communications between the parties.

5. At that meeting, Morris & Dickson presented DEA with a new settlement proposal, which it subsequently formalized into a term sheet sent to DEA on January 17, 2022.

6. Over the next several months, Morris & Dickson and DEA continued to engage in productive settlement discussions. On two occasions during this period, M&D traveled to Arlington for in-person meetings.

7. On November 18, 2022, Paul Dean, counsel for DEA, informed me that DEA could likely agree to one of Morris & Dickson's key requirements for a settlement: that M&D could keep its registration as part of a settlement. I conveyed that information to Morris & Dickson.

8. On May 18, 2023, a reporter from the Associated Press contacted Morris & Dickson, requesting to speak about why DEA had not acted on ALJ Charles Dorman's recommendation to revoke Morris & Dickson's DEA registrations (the "ALJ Recommendation"). Morris & Dickson promptly notified me of the Associated Press's request.

9. That same day, I spoke to DEA's counsel, who advised that he was not aware of anyone at DEA providing these documents to the reporter and that DEA generally viewed the administrative file as FOIA exempt until after issuance of a final order, which had not yet been issued.

10. On May 19, 2023, I spoke to the reporter, who informed me that he had been in contact with DEA. He also told me he was in possession of a leaked copy of the ALJ Recommendation and other unspecified documents from the confidential administrative file. The reporter said the ALJ Recommendation came from an unknown source.

11. Later that day, I spoke again to DEA's counsel, who advised that his "front office" approved the resumption of settlement communications and would have no response to the reporter's inquiry.

12. One hour later, Morris & Dickson received via email an Order from the DEA Administrator adopting the ALJ Recommendation and revoking Morris & Dickson's registrations (the "Final Order"), which would become effective 30 days after the publication of that Order in the Federal Register.

13. On May 22, 2023, I communicated with the Associated Press reporter. He confirmed that he received some unspecified "new documents" and, as a result, the Associated Press was advancing publication of its story to the next day.

14. On May 23, 2023, the Associated Press published its story, confirming that it obtained a copy of the ALJ's Recommendation to the DEA Administrator and that the Administrator had issued the Final Order revoking Morris & Dickson's DEA registrations.

15. Notice of the Administrator's order was not published until May 26, 2023.

Respectfully submitted this 2nd day of June, 2023.

/s/ Jim Walden
Jim Walden